EXHIBIT D

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, *et al.,*

Plaintiffs,

v.

DONALD J. TRUMP, *et al.,*

Defendants.

Case No: 3:25-cv-4737

DECLARATION OF KIMBERLY PENDLETON

I, Kimberly Pendleton, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, as follows:

1. I am the Director of the Division of Grants, Agreements, and Acquisition Support (DGAAS-Grants) within the Food and Drug Administration (FDA), a component of the U.S. Department of Health and Human Services (HHS).

2. In this role, I am responsible for, among other things, monitoring administrative and fiscal aspects of FDA's grant and cooperative agreements; assuring compliance with Federal laws and HHS administrative policies and procedures; and maintaining official grant files for grant awards. In this role, I have oversight of the entirety of FDA's grants management branch and process, am kept abreast of all of FDA's grantees, and review all agency correspondence pertaining to grant awards, including those to the University of California.

3. This declaration is based upon my personal knowledge, information acquired by me in the course of performing my official duties, information contained in the records and systems of FDA to which I have access in the course of my duties, and information conveyed to me by other knowledgeable FDA employees with whom I work on a regular basis.

4. I submit this declaration in response to the Court's June 12, 2025 order in the above-captioned matter requiring expedited discovery concerning: (1.a) "the policy for selecting grants for termination at [FDA]"; (1.b) "The overarching Executive Order(s) or directive(s) animating the termination policy at [FDA]"; (1.c) "The way in which the policy or overarching priority was communicated to each agency and by whom"; (1.d) "The way in which the termination policy was implemented at [FDA] (e.g., keyword searches, AI tools, etc.)"; and (2) "an estimate of the number of

grants issued to the University of California Regents or specific UC campuses that were terminated between January 20, 2025 and the present."

5. My responses are presented out of sequence in an attempt to correct any misunderstandings and to better explain FDA's termination of grants to UC entities and its polices concerning the termination of grants, or rather lack thereof.

6. At the outset, it is important to understand the difference between a grant and a contract, which are distinct funding mechanisms. A grant is used when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant is the recipient, as a proxy for the public, as opposed to the Federal government. A contract is used when the principal purpose of a transaction is acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal government. The primary beneficiary under a contract is the Federal government. In other words, grants are used when the benefit is for the public, and contracts are used when the benefit is for the Federal government.[1]

7. Grants and contracts are administered separately within FDA using separate teams and systems.

8. Between January 20, 2025 to the present, FDA has not terminated any of its grants with UC entities (i.e., grant awards where a UC entity is listed as the primary grantee). FDA currently has a total of approximately 21 grants with UC entities. I am not aware of any plans to terminate any grants to any UC entity.

9. To the best of my knowledge, FDA does not have specific policies concerning the selection of grants (to UC or any other entity) for termination. General procedures concerning the termination of grants are set out in HHS's Grants Policy Statement, attached hereto as "Exhibit 1."

10. To the best of my knowledge, FDA does not have distinct policies implementing this Administration's executive orders concerning grants and contracts. Instead, based on my experience, these executive orders are implemented individually, meaning that when an executive order is issued that may impact FDA grants or contracts, it is communicated via an emailed directive from the relevant component of the Office of the Secretary to the appropriate team. For executive orders involving FDA grants, the DGAAS-Grants team would handle implementation by querying the relevant databases using keywords to identify the relevant grants and entities and initiating the appropriate next-steps.

[1] The FDA "grant" referenced in Plaintiffs' Pimentel Declaration is in fact a contract between FDA and Columbia University; the University of California Berkeley is designated as a subcontractor to that agreement. *See* Dkt. 15.

Executed on June 17, 2025 in Rockville, Maryland.

Kimberly Pendleton

Kimberly Pendleton

HHS Grants Policy Statement

Effective date: April 16, 2025

This HHS Grants Policy Statement (GPS) replaces all prior versions

Contact grantpolicyreq@hhs.gov with GPS feedback

Contents

Introduction and General Information

The Grants Policy Statement (GPS) is incorporated by reference in the official Notice of Award (NoA) as a standard term and condition.

The GPS provides information on HHS agencies that make awards, the award process, and where to find and apply for awards. The GPS also provides information about the legal and regulatory rules that apply to your award and will be used for enforcement purposes. The GPS will be updated to reflect changes in law and policy.

The latest version of the GPS is at www.hhs.gov/grants/grants/grants-policies-regulations/index.html and it includes:

- Introduction and General Information
- Pre-Award
- Post-Award
- Single Audit
- Appendices

    A. Awarding Agency Overview
    B. Abbreviations and Glossary
    C. Post-Award Considerations by Type of Program, Activity, or Recipient
    D. HHS Administrative and National Policy Requirements
    E. Financial Assistance General Certifications and Representations

Supersession

This GPS replaces the HHS Grants Policy Statement dated January 1, 2007.

This GPS reflects the current 45 CFR part 75 regulation and eight flexibilities from 2 CFR part 200 (effective October 1, 2024). It will be updated in 2025 to reflect the HHS adoption of 2 CFR part 200 in its entirety and the retention of certain HHS specific provisions in 2 CFR part 300. From this date on, HHS plans to update the GPS annually to make sure it reflects changes in statutes, regulations, and policies.

Applicability

The 2024 HHS GPS applies to awards and award modifications that add funding made on or after April 16, 2025. This includes supplements to award, competing and non-competing continuations. The GPS applies to all HHS recipients and the requirements flow down to subrecipients.

The HHS GPS does not apply to awards made by the National Institutes for Health (NIH). For NIH awards, please see the National Institutes of Health Grants Policy Statement (NIHGPS), which is the policy document describing the requirements that serve as the terms and conditions of NIH awards.

The HHS GPS does not apply to non-discretionary awards or to awards made to individuals. HHS agencies have the discretion to apply certain parts of the GPS to non-discretionary awards and other policies to your non-discretionary or individual award.

Agencies that administer HHS awards include:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

See Appendix A for more information.

Requirements

The following impose requirements on your award and are addressed in the GPS:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75)
- Eight provisions of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200):

    1. 2 CFR § 200.1 Modified Total Direct Cost Definition, Equipment Definition, Supplies Definition
    2. 2 CFR § 200.313(e) Equipment Disposition
    3. 2 CFR § 200.314(a) Supply Disposition
    4. 2 CFR § 200.320 Micro-purchase Threshold
    5. 2 CFR § 200.333 Fixed Amount Subawards Amount
    6. 2 CFR § 200.344 Closeout Provisions
    7. 2 CFR § 200.414(f) Indirect Cost Rate Provisions
    8. 2 CFR § 200.501 Audit Provisions

- The Notice of Award (NoA)
- The Notice of Funding Opportunity (NOFO), if stated in the NOA

Other regulations or statutes with more requirements might apply to your award. These include:

- Grants for Research Projects 42 CFR part 52
- Procedures of the Departmental Grant Appeals Board 45 CFR part 16
- Claims Collection 45 CFR part 30
- Equal Treatment for Faith-Based Organizations 45 CFR part 87
- Restrictions on Lobbying 45 CFR part 93
- Metric Conversion Policy for Federal Agencies 15 CFR part 273
- Public Health Service Policies on Research Misconduct 42 CFR part 93
- Protection of Human Subjects, 45 CFR part 46

See Appendix D for more information.

Terms and Conditions

HHS states the requirements of an award in the award terms and conditions:

- The GPS is incorporated by reference as a standard term and condition of awards.
- The NoA includes all terms and conditions of a specific award.
- Notice of Funding Opportunities (NOFOs) describe program requirements, which may be included as terms and conditions.

Types of HHS Awards

Awards fall into two main types:

- Discretionary: HHS chooses who gets the award and how much. Selection of these awards are generally competitive. The amount of an award can be competitive or by a set formula. Types of discretionary awards include research, training, services, construction, and conference support.
- Non-discretionary: A statute determines the recipients and amounts, either directly or by a formula (i.e., each State gets an award of a certain amount). This includes block grants and entitlement programs.

Award Instruments

Award instruments are legal agreements between an awarding agency and a recipient. The two kinds generally addressed in the GPS are:

- Grants: The awarding agency is not substantially involved in the project (31 USC 6302, 6304).
- Cooperative agreements: The awarding agency is substantially involved in the project (31 USC 6302, 6305).

Roles and Responsibilities

This section highlights roles and responsibilities. The GPS supplies more details throughout.

Recipient Roles and Responsibilities

Recipients manage performance and funds. Required roles are:

- Authorized Organizational Representative (AOR): The AOR has authority to act for the organization and is responsible for meeting award requirements, properly managing the award, and providing oversight. The AOR's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- Principal Investigator or Project Director (PI/PD): The PI/PD is the individual(s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.

Awarding Agency Roles and Responsibilities

HHS is responsible to Congress and U.S taxpayers for carrying out its mission in a cost-effective and compliant way. The HHS agencies that administer awards have grants offices and staff designated to conduct this work. The roles and responsibilities of HHS staff (at each awarding agency) include:

- Grants Management Officer (GMO): The GMO is the official who handles the non-program parts of an award for the HHS agency. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the HHS awarding agency to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
- Grants Management Specialist (GMS): Acts as the main grants administration contact for recipients. Handles administrative activities on behalf of the GMO. The GMS contact information can be found on the NoA.
- Project Officer or Program Official (PO): Responsible for the programmatic, scientific, and technical sides of award programs, including oversight and monitoring. The PO contact information can be found on the NoA.
- Review Administrator (RA): Provides oversight of the application review process, although not all agencies have this role.

Pre-Award

This section helps you find funding opportunities, prepare, and apply.

Locating Funding Opportunities

Agencies announce competitive funding opportunities. All discretionary Notice of Funding Opportunities are listed on Grants.gov**.** There are three other ways to find more information about HHS financial assistance.

Grants.gov, Forecasts, and the Notice of Funding Opportunity (NOFO)

HHS policy requires maximum competition for discretionary grants to the greatest extent possible. As such, HHS agencies promote the widest and earliest possible spread of information through forecasts of upcoming grant opportunities and NOFOs. Awarding agencies post discretionary or competitive NOFOs at Grants.gov.

Grants.gov forecasting is the direct way to find NOFOs. NOFOs are usually open for at least 60 days. Only rarely are they open for fewer than 30 days.

Because HHS aims for the widest and earliest possible spread of information, HHS agencies post future opportunities on Grants.gov through forecasts. Forecasts may be posted weeks or months before NOFOs. Forecasted NOFOs can be found in the Grants.gov search page by clicking the "forecasted" button. Forecasts include helpful information such as:

- expected number of awards
- estimated award amounts
- description of the program
- estimated NOFO posting date
- estimated application due date
- estimated project start date and period of performance

How to Subscribe to HHS Grants Forecast

When you create a Grants.gov account, you can customize the type of email notifications you receive. Log in and then go to the subscription page to sign up for news updates about system enhancements, notifications about saved searches, new funding opportunities, and more.

Awarding Agency Websites

Most awarding agencies have award web pages. See Appendix A.

SAM.gov and Assistance Listings

Assistance listings are public descriptions of federal assistance programs. All assistance listings are included on the System for Award Management (SAM.gov), a site run by the U.S. General Services Administration. Search assistance listings at SAM.gov.

Preparing to Apply

The first step is to read the entire NOFO and the links in it. Each part of the NOFO sets out basic information for that award.

To apply, you must:

- be an eligible entity
- address the NOFO requirements
- submit a complete and compliant application by the deadline(s)

General Eligibility Considerations

In general, HHS awards may be made to domestic public or private, non-profit or for-profit organizations. Foreign or international organizations are eligible for research awards, or if expressly authorized by law.

The NOFO includes specific eligibility criteria and any requirements to prove eligibility. Applicant eligibility criteria for all HHS NOFOs are almost always based on statute or program regulation.

HHS policy requires open competition to the greatest extent possible. Restricting eligibility, as compared to statute or program regulations, is only done with appropriate justification in rare cases.

Agencies review applications for eligibility when they receive them. The AOR signature generally serves as assurance of eligibility, unless additional proof of eligibility is required in the NOFO. If the applicant is not eligible, the application will not be reviewed.

Additional Eligibility Restrictions

Concurrent Applications

You cannot apply for funding for the same project or activities from multiple HHS Public Health Service (PHS) agencies at the same time. If you do, your applications will be returned. See Appendix A for a list of PHS agencies.

Suspension, Debarment, and Exclusion

Agencies are required to check SAM.gov for individuals and organizations that are debarred, suspended, declared ineligible, or voluntarily excluded from receiving HHS award funds. HHS will not give awards to or pay these individuals and entities, including recipients and subrecipients. If such an individual is involved in an award, costs like their salary are not allowed.

Applicants must disclose if any of the following conditions apply to their organization, planned staff or principals (as defined in 2 CFR § 180.995), including Principal Investigators (PIs), and other key personnel:

- Are currently excluded or disqualified;
- Were convicted within the previous three years of any offenses listed in 2 CFR § 180.800(a) or had a civil judgment for one of those offenses during that time;
- Are currently indicted for or otherwise facing criminal or civil charges by a governmental entity (federal, state, or local) for any of the offenses listed in 2 CFR § 180.800(a); or,
- Have had any public transactions (federal, state, or local) terminated within the previous three years for cause or default.

Recipients of HHS awards must also make subrecipient organizations and subrecipient participants follow federal Debarment and Suspension regulations (2 CFR part 376 and 2 CFR part 180). These participants can include:

- Consortiums
- Subcontracts
- Consultants
- Collaborators
- Contractors that require the provision of goods or services that will equal or exceed $25,000

These subrecipients must also make sure that anyone they hire with award funds follow the same rules. Before entering into an agreement, these participants should tell the award recipient if he, she, or any principals are excluded or disqualified at that time.

Ultimately, it is the job of the applicant or recipient to make sure none of the subrecipient and principals involved are excluded or disqualified. Award recipients cannot make a transaction with someone who is disqualified unless they get an exception under the disqualifying statute, Executive Order, or regulation from HHS.

For more information, see Suspension and Debarment at 45 CFR § 75.213, 2 CFR part 180 and 2 CFR part 376.

Delinquency on Federal Debt

If an entity or individual owes money to the U.S. with a lien, they cannot get an award. Applicants must state in their applications whether they are delinquent on any federal debts. Agencies may delay awards until federal debts are settled.

Do not include a person in the application if they have unpaid federal debts with a lien. Agencies will disallow costs for these individuals.

See 28 U.S.C. 3201(e).

Lobbying Prohibition

Applicants must certify they will not use federal funds to pay any person to influence agency staff, Congress members, and officers or employees of Congress about federal awards.

Applicants with total proposed costs of more than $100,000 must certify that they:

- have not made unallowable lobbying payments,
- will be responsible for reporting on non-federal funds used for lobbying,
- will include these requirements in consortium agreements, subawards, and contracts of more than $100,000 under their award.

See 2 CFR part 93, 2 CFR § 200.450, and the SF-424 for more about lobbying requirements.

HHS Application Process

Types of Applications

HHS uses these application types:

- New application: A request for funds for new activities. It can be competitive or not.
- Non-competing continuation application: A request for funds for the next budget period(s) within a period of performance. Agencies provide an NoA with new budget details.
- Competing continuation or renewal application: A request to continue a project that is ending with a new period of performance. This is competitive.
- Supplemental application: A request for more funds in the current budget period. This can be for changes in the project scope, expansion of already approved activities, or for unexpected costs.
- Revised application: A previously not funded application updated and submitted again for review.

Pre-applications and Letters of Intent

Before a full application, an agency might ask for:

- Pre-applications: Used to filter out applicants that will be unlikely to receive funding through an objective review. This saves time before writing a full application.
- Letters of Intent: Agencies might want notice that you plan to apply. This is usually optional and doesn't mean you have to apply. It's mostly to gauge interest and help the HHS agency estimate how many applications to expect.

Application Forms

Forms and instructions are on Grants.gov. You can find a NOFO's required forms in the application package in Grants.gov. The NOFO is your best source when completing forms. The NOFO agency contact, located on the NOFO, can answer any questions you may have.

Application Budgets

You will need to include a budget as part of your application. Some applications require a detailed budget. The NOFO will describe the budget requirements. For HHS budgets, applicants and recipients need to understand:

- The costs allowable under the program
- The relevant cost principles
- The difference between direct and indirect costs
- When you need an indirect cost rate or research patient care cost rate, and
- Any matching or cost sharing requirements

Project costs include allowable direct costs plus allocable indirect costs, minus applicable credits. See below Cost Principles, Direct Costs and Indirect Costs sections of the GPS.

Cost allowability is subject to the governing statute, program regulations, and award terms and conditions. There are situations when HHS will not reimburse indirect costs.

Cost Principles

Developing an application budget depends on understanding what costs are allowable under HHS financial assistance programs.

For more information about how cost principles apply to your organization, see 45 CFR § 75.401.

This section on cost principles interprets the regulations at 45 CFR part 75 and is not all-inclusive.

Cost principles:

- Establish general standards for the allowability of costs.
- Provide guidance on treating costs as direct or indirect.
- Provide principles for selected items of cost.

The cost principles apply to all recipients.

You can use your own accounting system to implement the cost principles if you meet the standards for financial management systems at 45 CFR § 75.302.

The federal-wide cost principles are in 45 CFR part 75, subpart E.

The cost principles for:

- Hospitals are at 45 CFR part 75 Appendix IX
- For-profit organizations are at 48 CFR § 31.2

If specifically identified, use the applicable cost principles for your type of organization. Cases where the cost principles do not apply are listed in 45 CFR § 75.401(a).

Is It Allowed?

As the HHS agency official for the non-program parts of awards, the Grants Management Officer (GMO) makes the final determination on allowability.

For all allowability requirements see 45 CFR § 75.403. Following is a summary.

A cost is allowable if all the following apply:

- It is necessary and reasonable for award performance.
- It complies with any limitations or exclusions in the cost principles or the federal award about types or amounts of cost items.
- It is consistent with policies and procedures across all recipient activities, regardless of source of funding.
- It is consistent across all activities in identifying direct and indirect costs.

- It follows generally accepted accounting principles (GAAP). See 45 CFR § 75.403(e) for exceptions.
- It is not used for cost-sharing requirements of another federally financed program, unless specifically allowed by law.
- You maintain required documentation.

Is It Reasonable?

For all reasonableness requirements see 45 CFR §75.404. Following is a summary.

Considerations for reasonableness include:

- If the cost is generally recognized as ordinary and necessary.
- The requirements of:
    - Sound business practices
    - Arm's-length bargaining
    - Federal, state, local, tribal, and other laws and regulations
    - Terms and conditions of the federal award
- If the cost aligns with market prices for comparable goods or services in the geographic area.
- The cost does not significantly deviate from your established practices and policies regarding such costs, regardless of source of funding.

Allocability

Allocability in grants means costs that can be applied to your award. For all allocability requirements see 45 CFR § 75.405. Following is a summary.

A cost is allocable if any of the following apply:

- It is spent only for the work under a federal award.
- It benefits both the federal award and other recipient work and can be distributed using reasonable methods.
- It is necessary to your overall operations and can be assigned to the federal award.

Direct and Indirect Costs

Costs can be direct or indirect:

- Direct costs: Directly related to the cost of the project or project activities. These costs are based on actual expenses or easily estimated accurately. Examples of direct costs are generally salaries, travel, equipment, and supplies directly for grant activities.
- Indirect costs: Not readily tied directly to the project or project activities. If a cost is indirect, it cannot also be listed as a direct cost for any federal award. Examples may be facilities operation and maintenance costs, depreciation, and administrative

expenses. You must have or negotiate an indirect cost rate to reimburse indirect costs.

See 45 CFR §§ 75.413-414, and 45 CFR § 200.414.

Indirect Cost Rates

As stated above, indirect costs are for common activities that cannot be specifically tied to a particular project. Examples include facilities operation and maintenance costs, depreciation, and administrative expenses. You must treat costs as direct or indirect consistently.

Indirect costs are allowable under most HHS awards and are charged as a rate. There are three ways indirect costs may work:

- Specified rate. The rate may be specified in statute, regulations, or policy. If this is so, the difference between the specified rate and the negotiated rate can satisfy match or cost sharing requirements. There are three HHS-specific specified rates to consider:
- Training grants, including career awards, are limited to 8%.
- Indirect costs to foreign organizations and foreign public entities when the awarded work is performed fully outside of the territorial limits of the U.S. are limited to 8%.
- Negotiated Indirect Cost Rate Agreement (NICRA). You can negotiate a rate with your cognizant federal agency. If the cognizant agency is HHS, a rate is negotiated by Program Support Center Cost Allocation Services (CAS) or the Division of Financial Advisory Services (DFAS) in the NIH Office of Acquisition Management and Policy (responsible for negotiating indirect cost rates for for-profit recipients). Indirect cost proposals must use the applicable cost principles and cognizant agency guidance.
    - See 45 CFR part 75, Appendix III for institutions of higher education.
    - See 45 CFR part 75, Appendix IV for non-profits.
    - See 45 CFR part 75, Appendix V for state and local government cost allocation plans.
    - See 45 CFR part 75, Appendix VI for public assistance.
    - See 45 CFR part 75, Appendix VII for state and local governments and Indian Tribe indirect cost plans.
- De minimis rate. If you do not have a NICRA, you can use the de minimis rate indefinitely. We are applying the newly revised rate, in 2 CFR § 200.414(f), of 15% of modified direct costs. Modified direct costs are salaries and wages, fringe benefits, materials and supplies, services, travel, and no more than $50,000 of each subaward, minus some exclusions. See 2 CFR § 200.2 for the full definition. See 2 CFR § 200.414 for more on the de minimis rate.

The de minimis rate is not applicable for some recipients. These recipients include governmental agencies that receive more than $35 million in direct funding and Indian tribal governments. See 2 CFR Appendix VII to § 200 D.1.b.

Exclusions

Some HHS awards and recipients are not eligible for indirect cost reimbursement. This will be described in the NOFO.

Indirect costs are not paid for:

- Grants to federal institutions, 45 CFR § 75.217(b)(3)
- Grants to individuals, including fellowships, scholarships, traineeships, or fixed amounts like educational allowances or tuition and fees, 45 CFR § 75.2 (Definition of Micro-Purchase Threshold).

Pass-through Entities

Pass-through entities must use their subrecipient's federal NICRA. A 15% de minimis rate may be used if there is no federally negotiated agreement. See 2 CFR § 200.414.

Salary Rate Limit (SRL)

Generally, the HHS Appropriations Act includes an SRL. This statutory requirement limits the amount of funds under a grant or other extramural mechanism that can be used to pay individual salaries (including executive salaries) at a rate above the Executive Level II. Recipients may pay salaries at a rate higher than the Executive Level II if the amount beyond the HHS SRL is paid with non-HHS funds. Since the Executive Level II rate and HHS Appropriations Act citation changes each year, HHS refers to the Office of Personnel Management (OPM) posting the most recent information at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/exec/html/EX.aspx.

The HHS SRL applies to:

- The majority of HHS awards.
- Both direct and indirect costs under applicable HHS awards.

Effective October 1, 2024, when HHS is the cognizant agency for indirect costs or when HHS is acting as the shared-service provider for another cognizant agency for indirect costs, the HHS component that reviews and negotiates indirect cost rate proposals and cost allocation plans will issue NICRAs that incorporate the HHS SRL, to comply with the HHS Appropriations Act requirement.

Beginning with HHS awards, including continuation and supplemental awards, made on or after October 1, 2024, HHS recipients that do not have an approved indirect cost rate that complies with the HHS SRL requirement must take and document the following actions.:

- Identify any HHS award where HHS funds are used to pay any salary that exceeds the SRL using the HHS award. This includes both direct and indirect costs, both in whole and any portion of a salary that at a full-time equivalent exceeds the SRL.
- Have written policies and procedures that ensure the recipient does not draw down HHS award funds, whether as direct or indirect costs, to pay for salaries above the HHS SRL.

This may occur because the NICRA was issued before October 1, 2024, and it is not yet up for renewal, OR because the NICRA was issued by another cognizant agency for indirect costs that does not have an identical SRL.

A recipient may request a companion rate on the NICRA from HHS that does not incorporate the HHS SRL if:

- HHS is their cognizant agency for indirect costs or HHS is the shared-service provider for their cognizant agency for indirect costs; and
- The recipient is applying for an award from another Federal agency or from a program not subject to the HHS SRL.

Cost Sharing

Cost sharing refers to project costs that are not funded by the HHS agency. It is also sometimes called "match."

Cost sharing can be voluntary or can be required by statute or regulation.

NOFOs include information about:

- Whether there is required or voluntary cost sharing
- The agency's approach to looking at cost sharing during the application review
- Any caps on the agency's portion of total award costs
- Any restrictions on the types of funding that are acceptable as cost-sharing (e.g., in-kind contributions)
- Required documents, like commitment letters

See more on cost-sharing requirements at 45 CFR § 75.306.

Program Income and Third-Party Reimbursement

Program income is money a recipient earns that is both:

- Earned during the period of performance
- Earned directly from an activity funded by the award or due to the award

This can include money earned from things like:

- Services performed under the award,
- Renting property bought with award funds,
- Selling items made with award funds,
- Third-party reimbursement, such as payments for health services, and fees based on ability to pay,
- Principal and interest on loans made with award funds, and
- Royalties from patents and copyrights.

It does not include:

- Interest earned on advances of Federal funds or things like rebates, credits, discounts, and interest earned on any of them unless stated otherwise in the NOFO or NoA.

The full definition for program income is found at 45 CFR § 75.2 "Program income"

NOFOs might ask for estimated program income in the budget. NOFOs explain how to use expected program income.

There are no requirements for what to do with income earned after the end of the award period of performance, unless the NOFO or NoA says otherwise.

See more on the treatment of program income at 45 CFR § 75.307.

Unique Entity Identifier (UEI) and Registering in SAM.gov

Every applicant needs a Unique Entity ID (UEI) from SAM.gov.

- For a new UEI, register on SAM.gov. You'll get an email when it's active. This can take time.
- If you already have a UEI, renew on SAM.gov yearly.
- Keep your SAM registration details current.
- Make sure that your SAM registration is accurate for both contracts and grants.

For more information, see Get Ready for Grants Management at HHS.gov.

State and Local Review Requirements

Federal rules allow state and local governments and health agencies to review and comment on applications. You will find the requirements in the NOFO. There are two types of reviews:

- Intergovernmental review. Executive Order 12372 and 45 CFR part 100 allow for intergovernmental review by state and local governments through the State Single Point of Contact (SPOC).
- Public health system reporting. This reporting provides state and local health agencies with information on applications by health care delivery programs. If a state or local health official wants to review a full application, the official contacts the SPOC.

Contact your SPOC to learn more. Find SPOCs at the Office of Management and Budget website. Not all states have this process.

Applying

In almost all cases, you will need to submit applications online. All HHS agencies are required to post their competitive NOFOs on Grants.gov and will also post there how to apply online.

Agencies will not review applications that are from ineligible applicants, incomplete, are not compliant, or are not responsive to program requirements.

Send your application by the NOFO's deadline. If you are late, it will almost always be deemed non-compliant and will not be reviewed.

The AOR's signature on an application certifies that:

- The information in it is truthful, complete, and accurate,
- The applicant will comply with all required certifications and assurances,
- The applicant will comply with terms and conditions when accepting an award, and
- The non-federal entity is aware that any false, fictitious, or fraudulent statements or claims may subject the applicant to criminal, civil, or administrative penalties.

Some agencies might allow paper or email submissions. The NOFO will explain exemption requests. These are rare.

> PLEASE NOTE: Applicants must register with Grants.gov. For how to register with Grants.gov, see Registering an Organization or contact the Grants.gov contact center at 1-800-518-4726 or support@grants.gov. Registering can take up to one month.

Application Receipt and Review

Initial Eligibility Review

The awarding agency screens applications for eligibility. Unless the NOFO requires specific proof of eligibility, the AOR's application certification is enough.

Use of Application Information

Agencies protect your application information during merit review and in accordance with laws like the Freedom of Information Act and Privacy Act of 1974. Once awarded, the government can only use or share data as federal law allows. To help safeguard your information:

- Avoid sharing personally identifiable information.
- Only add confidential information if necessary.

See the Access to Research Data section of the GPS.

Merit Review

Merit review is a review by those with expertise in the programmatic subject matter area for the submitted applications.

Applications for discretionary programs, whether received in response to a NOFO, requested from a single source (very rare), or received as an unsolicited request for grant funding, will go through a merit review.

The merit review provides recommendations to the individuals responsible for making award decisions. Merit review is necessary to make sure HHS choses applications that best meet the needs of

the program. These needs must be based on what the NOFO says about what makes a successful application.

Peer review is a form of merit review. Reviewers are peers with expert knowledge about how the program topic. Sometimes, the program statute may tell us which type of reviewers to pick or how a review should happen.

Award Risk and Business Review

Before award, agencies do pre-award risk and business reviews of applications. These can include:

- Cost analysis of the budget
- Assessment of management systems
- Final review of applicant eligibility
- Compliance with public policy requirements

During this review, the agency might request more details or actions from you.

Following review, officials make decisions about making the award, adding special conditions, and funding level.

Cost Analysis

HHS agencies careful review of the applicant budget includes:

- a review of the cost breakdowns
- a check to make sure the cost data in the application is correct
- an overall review of the costs for need for and the reasonableness and allowability of proposed costs

The review depth depends on project complexity, applicant prior experience, and other factors.

Management System Analysis

Applicants must have systems, policies, and procedures in place to manage award funds and activities. HHS agency staff take a close look at your financial and business management systems. This review includes property management and procurement systems and helps ensure:

- Applicant organizations apply policies and procedures consistently, regardless of funding source, and
- Systems meet the standards and requirements in 45 CFR § 75.302, Financial Management.

Civil Rights Assurance

Domestic recipients, subrecipients, and contractors must file Form HHS 690, Assurance of Compliance once with the HHS Office for Civil Rights (OCR). It is not needed for each application.

The recipient must ensure that subrecipients and contractors have filed the form.

Additionally, recipients must comply with all applicable Federal anti-discrimination laws material to the

government's payment decisions for purposes of 31 U.S.C. § 372(b)(4).

(1) Definitions. As used in this clause –

(a) DEI means "diversity, equity, and inclusion."

(b) DEIA means "diversity, equity, inclusion, and accessibility."

(c) Discriminatory equity ideology has the meaning set forth in Section 2(b) of Executive Order 14190 of January 29, 2025.

(d) Discriminatory prohibited boycott means refusing to deal, cutting commercial relations, or otherwise limiting commercial relations specifically with Israeli companies or with companies doing business in or with Israel or authorized by, licensed by, or organized under the laws of Israel to do business.

(e) Federal anti-discrimination laws means Federal civil rights law that protect individual Americans from discrimination on the basis of race, color, sex, religion, and national origin.

(2) Grant award certification.

(a) By accepting the grant award, recipients are certifying that:

(i) They do not, and will not during the term of this financial assistance award, operate any programs that advance or promote DEI, DEIA, or discriminatory equity ideology in violation of Federal anti-discrimination laws; and

(ii) They do not engage in, and will not during the term of this award engage in, a discriminatory prohibited boycott.

(3) HHS reserves the right to terminate financial assistance awards and claw back all funds if the recipients, during the term of this award, operate any program in violation of Federal anti-discriminatory laws or engages in prohibited boycott.

Human Subjects and Animal Welfare Assurance

If IRB review and approval is required but still pending at the time of award, agencies will restrict human subjects research until they get and approve the needed proof. Additional information is available on the Office of Human Research Protections website. This includes a series of decision charts to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

Before getting an award, if applicants plan to use vertebrate animals, they must send an Animal Welfare Assurance to HHS' Office of Laboratory Animal Welfare. This confirms that a committee has reviewed the parts of the application related to animals.

Communicating Decisions

Agencies inform applicants about their decisions in various ways:

- Award: If you are getting an award, you will receive a Notice of Award (NoA).
- Denial: If the agency decides not to fund your application, the AOR gets a letter.
- Approved unfunded: Sometimes, despite a good review, there's not enough funds.

The awarding agency could keep your application for future funding. The awarding agency will notify the AOR that your application is approved but unfunded.

- Revised application eligibility: If not successful, the NOFO might allow you to adjust and reapply later. However, some agencies cap the number of revisions and retries.

You cannot appeal a denial or the amount of funds awarded.

The Notice of Award

The Notice of Award is a legal instrument. See 45 CFR § 75.210 for the contents of an NoA.

Accepting the Award

Once accepted, the contents of NoAs are binding.

Applicants become recipients when the NoA is signed by the awarding agency's Chief Grants Management Officer (CGMO) or his/her delegate. The recipient accepts an award by drawing down funds. HHS expects recipients to draw down funds in the first 30 days of the period of performance.

Declining or Negotiating Awards

During the time between the NoA being signed and the drawing down of funds, if you can no longer accept an award or you need to negotiate any award parts, tell the awarding agency. If no agreement is reached, the agency will cancel the award. You cannot challenge the agency's decisions on the terms and conditions.

Periods of Performance

HHS uses the period of performance system for funding awards. Funding is provided in approved yearly increments called budget periods. The total period of performance includes the initial competitive

segment, any additional segments authorized by approved continuation applications, and any no-cost extensions.

A competitive segment usually will be no longer than five years, not including no-cost extensions. A single federal award for the entire period of support may be used if the project is only construction or modernization or if the total planned project will be less than 18 months.

The awarding agency will determine the length of the period of performance based on:

- Any statutory, regulatory, or administrative requirements,
- The length of time requested by the applicant,
- Any time limits on the period of performance recommended by merit review,
- The frequency of merit review, and
- The funding principles as specified in the NOFO.

The NoA generally approves a period of performance that goes beyond the current budget period, showing the HHS awarding agency's intention to continue providing support. Funding for future budget periods is not guaranteed at the level shown on the current NoA. There is no legal obligation for HHS awarding agencies to provide funding beyond the end date of the current budget period in the NoA.

Recipients must submit a continuation application or annual report to get approval and funding for each new budget period within the approved period of performance. The HHS agency will make its decision to fund the next budget period by issuing a NoA which shows the new budget period and amount of new funding. Funding is based on adequate performance, availability of funding, and the best interests of the federal government.

Budget periods usually last 12 months. However, they may be shorter or longer based on programmatic or administrative needs. The NoA will show the total approved budget for the applicable budget period. This includes direct costs, applicable indirect costs, and any required matching or cost sharing.

Costs in the NoA

The initial NoA and each subsequent NoA provide details of the award and the amount awarded. After the initial budget period, NoAs may reflect any authorized carryover and amounts previously awarded for the full period of performance. The amount awarded is shown either as total direct and indirect costs and as a categorical (line item) budget breakdown. This is based on the requirements in the NOFO.

Recipients have certain rebudgeting flexibility within the overall amount awarded. However, the total amount awarded is the maximum amount the awarding agency is obligated to pay under that award. Once an award is made, the HHS awarding agency is not required to provide any supplemental or additional funding.

Post-Award

As a recipient, you will manage HHS awards and activities including:

- Project performance, 45 CFR § 75.301 and 2 CFR § 200.202

- Use of award funds
- Compliance with award terms and conditions
- Issuing and monitoring subawards per 45 CFR § 75.352

Recipient internal controls and policies must meet 45 CFR § 75.303.

Awarding agency staff monitor recipients for compliance, performance, and need for technical assistance. Reviews include:

- Recipient reports
- Financial and progress reports
- Audit reports
- Correspondence,
- Onsite and remote site visits, and
- Other information.

The Notice of Award supplies HHS contact information and instructions for reporting.

Changes to Awards

Prior Approvals

At times, you may need to make changes to the program budget or activities. Some changes require prior written approval. To find out if a change needs prior approval:

- Carefully review your NoA.
- Review 45 CFR § 75.407 for actions needing prior approval.
- Review Appendix E of the GPS for prior approval requirements for certain types of awards.
- Ask your GMS if you are not sure.
- Ask your cognizant agency for indirect costs if you have questions about changes to indirect costs. The cognizant agency is the federal agency that approved your indirect cost proposal.

Seeking Prior Approval

Once you know that you need prior approval, you can request it from your GMS. Prior approval requests must include:

- Recipient name
- Principal investigator (PI) or project director (PD) and authorized organizational representative (AOR) name
- PI or PD and AOR telephone numbers and e-mail addresses

You must send your prior approval requests in writing, by mail, prior approval system, or email. It must:

- Be signed by the AOR (if sent in an email, attach the signed letter/memo)
- Include any necessary supporting documentation
- Get to the awarding agency in enough time for approval before making the change

Once received, the awarding agency GMO or his or her designee will review and approve or deny the request:

- If the GMO or GMS decides the change does not actually require prior approval, the awarding agency must promptly inform you.
- If prior approval is required, the GMS will send a decision to the AOR with a copy to the PI or PD within 30 calendar days of receipt.

Only the GMO or GMS, as the GMO's delegate, can issue written approval. Informal answers are not valid.

There is no appeal for denial of a prior approval request.

Subrecipient Prior Approvals

The recipient has the authority to give prior approval for changes to sub-award or contract activities or budget. This does not include any action inconsistent with the award purpose or terms and conditions. The awarding agency must approve any actions that will result in a change to project scope. Ask the GMS if you have questions about a proposed change.

Budget and Scope Changes

Minor Budget Changes

Within a budget period, you can adjust your budget without prior approval if:

- The change is within or between approved direct cost categories.
- Your award's federal share is below the simplified acquisition threshold, and your NoA doesn't include a prior approval need. Check the current threshold in the Federal Acquisition Regulation (FAR) at 2.101, Definitions.

Significant Budget Changes

Significant budget changes require prior approval when they constitute a change of scope or exceed 25 percent of total direct costs of the last approved budget period. When you are not clear if your budget change is beyond the scope, call your GMS.

Expanded Authority

If expanded authority is not granted in your NoA, you do not have it. To know if you have any expanded authorities:

- Review your NoA. Expanded authorities may be adopted by reference.
- Review your specific award conditions. These may include expanded authorities or limits on them.

When using expanded authorities as granted in the NoA, make sure you follow award requirements and the cost principles. All changes are subject to monitoring, audit, and related remedies for noncompliance. See the section below.

For a full understanding, see 45 CFR § 75.308(d)(1). Expanded authorities may include:

- Waiving the prior approval requirements in 45 CFR part 75, except for those listed in 45 CFR § 75.308(c)(1); and
- Three specific waivers in 45 CFR § 75.308(d), including:
    - Incurring project costs up to 90 calendar days before award. Doing so is at the recipient's risk.
    - Carrying forward unobligated balances to the next budget period unless the funds are currently restricted. You need prior approval to carry forward any unobligated balance to any budget period other than the next budget period.
    - Initiating a one-time extension of the period of performance by up to 12 months unless any of the following are true:
        - The extension requires additional federal funds
        - The extension involves any change in the approved project objectives or scope

Recipients may not use a one-time extension only to use unobligated balances.

Please Note: For awards that support research, unless your awarding agency provides other instructions in the NoA in general or because it is part of a regulation, the three specific waivers above (in 45 CFR § 75.308(d)) are automatic and noted in your NoA.

Several expanded authorities have specific deadlines for reports or notification. If a recipient consistently fails to meet them, the awarding agency may stop their ability to use them. Be sure to read your NoA carefully or ask your GMS if you have questions about expanded authorities under your award.

Extensions to Awards

The awarding agency may provide more time and funds after an award is made. The two types of extensions are:

- No-cost extensions: A time extension without more funds.
- Funding extension with funds: A time extension with added funds.

No-Cost Extensions

HHS agency prior approval is required for no-cost extensions, unless provided as an expanded authority.

When prior approval is required, the recipient must request the no-cost extension no less than 10 days prior to the end of the budget period.

In cases where there is expanded authority, the recipient must notify the HHS agency in writing with the supporting reasons and a recommendation for revised period of performance at least 30 calendar days before the end of the period of performance in the original NoA.

Regardless of whether approval is required, no-cost extensions are not meant to just spend unobligated funds. The purpose of a no cost extension is to:

- complete the project,
- provide for an orderly shutdown, or
- in some cases, provide a bridge to the next award.

If using expanded authority, and you do not need permission, you must tell the awarding agency.

Reminders for All Extensions

- You can't extend a period already lengthened by the awarding agency.
- Award terms and conditions still apply during the extended time.
- No matter the extension length, you must keep sending required reports as set out in your award.
- You must update all necessary certifications and assurances, including those about human subjects and animal welfare, following relevant rules and policies.
- A second extension longer than 12 months should be rare and will need special justification.
- If the agency denies an extension, you cannot appeal it.

Supplemental Funding Extension Without Change in Scope

A recipient may request supplemental funding with an extension of time without a change in scope that is under 25% of the total approved budget or $250,000, whichever is less, for the period of performance. These extensions are not competitive. Approving a request is at the discretion of the agency and depends on availability of funds.

Supplemental Funding Extension with Change in Scope

For supplemental funding and an extension of time with a change in scope, you must submit the request at least 30 days before the period of performance ends. The request must include the proposed revised ending date and justify both the extension and any additional funds. These extensions are not competitive. However, the HHS agency will conduct a merit review and will have to internally justify the award.

Transferring Major Work to A Subrecipient

Non-Pass-Through Programs

For these awards, you have a substantial project role and cannot just be a conduit for another party.

Before transferring major or substantive work to a subrecipient not in the approved application, you must get prior approval. This does not apply to buying or obtaining regular goods or services.

When asking for prior approval, include:

- What activities or tasks you want to transfer.
- Why a third party should do them.
- A detailed cost estimate and reasons, including any indirect costs and their reimbursement method.
- How you'll choose the subrecipient.
- The type of subaward planned.
- The types of organizations you'll solicit. If you've already chosen one, name it and explain why.

Pass-Through Recipient

A pass-through recipient means a non-Federal recipient that provides a subaward to a subrecipient to carry out part of a Federal program. In a pass-through program, the recipient:

- Chooses subrecipients to deliver services.
- Coordinates and oversees their activities
- Gives needed administrative support to meet awarding agency requirements.

For these programs, you don't need prior approval to give a subaward.

Change in Recipient or Recipient Status

The following section addresses policies for changes in recipient organization, scope, status of key personnel, and organizational status.

Change of Recipient Organization

To transfer the legal and management responsibility of an award to another organization, you must get prior approval.

The awarding agency must ensure the award's purpose and scope remain the same and the transfer aligns with federal appropriations laws and the statute or authority for the underlying award.

HHS allows transfer to a new recipient organization if:

- The award to be transferred has been terminated per 45 CFR § 75.372.
- There is a successor in interest or name change. Please contact your GMS for more information about the difference between these two.
- The awarding agency holds back a non-competing continuation award for reasons other than the project's performance. This can relate to the recipient's award management or not meeting terms and conditions.
- The original recipient agrees to give up the award before the period of performance ends. This can happen if a PI moves to a different organization. The project, with the same PI, can continue up to the current period of performance but not beyond. Costs cannot exceed the approved direct and applicable indirect costs.

Send your request as soon as possible before the end of the approved budget period within the period of performance.

If you want a change in organization, you must get prior approval from the GMS and sometimes, the Office of General Counsel. Contact the GMS if you believe the award needs to go to a new organization, ideally a few months ahead. Early requests enable important discussions, smooth review of the request, and avoid delays.

Supporting Documentation Needed for Requests

From the original organization:

- The PHS 3734, "Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant," or an equivalent form from the awarding agency.
- For research awards, include a "Final Invention Statement and Certification."
- A final Federal Financial Report within 120 days after the end of HHS support.

From the proposed new organization, the awarding agency will request an application and will provide instructions for completing the application.

Requirements for Review and Possible Approval

Transfer requests are only considered when:

- All benefits of the original award, including equipment purchased fully or partly with award funds, are transferrable;
- The awarding agency decides there is a continued need;
- There is no change in the project's scope. If there is, it may need a merit review and possibly a different procedure;
- The facilities and resources at the new organization will allow for successful performance; and,
- For transfers to or between foreign or international organizations, any special approval requirements are met. This might include approval by an advisory council or board.

Even if the requirements above are met, the HHS agency may reject the request or terminate the award.

To implement a recipient change, the HHS agency:

- Sends a revised NoA to the original recipient, updating the budget and end dates;
- Removes any support for future years;
- Deobligates any remaining funds, based on the expenses from the relinquishing statement; and,
- Issues an NoA to the new recipient, reflecting the balance from the relinquishing statement.

Change in Scope

The PI/PD may want to make changes in the methodology, approach, or other aspects of the project that do not change the scope. The GMS must give prior approval for a proposed change in scope.

A change in scope occurs when the recipient proposes to change the objectives, aims, or purposes identified in the approved application. This might include:

- Shifting the research emphasis from one disease area to another;
- Changing the service area;
- Eliminating a primary care delivery site; or,
- Making budget changes that cause a project to change substantially.

The HHS agency makes the determination of whether a proposed change is a change in scope.

Change in Status of Key Personnel

Key personnel include the PI or PD and any other key personnel named in the NoA.

Provide written request to the GMS if any key personnel:

- Withdraw from the project entirely;
- Are absent from the project for a period of three months or more; or,
- Reduce time devoted to the project by 25 percent or more from the approved level.

The awarding agency must approve replacement of key personnel, or any alternate arrangement proposed.

A request for approval to substitute key personnel includes:

- A justification for the change
- The proposed person’s biography
- Other sources of support, if applicable
- Any budget changes resulting from the proposed change

If your proposed arrangements are not acceptable to the awarding agency, they may suspend or terminate the award. If unable to make suitable arrangements, you may relinquish the award. To do so, notify the GMS in writing. The GMS will forward closeout instructions.

Change in Organizational Status

You must inform the awarding agency ahead of time about specific changes in your organizational status to ensure a smooth transition and maintain compliance with administrative requirements. The following are the situations that require prior notification:

- Successor-in-interest: This happens when the obligations and rights of an award are acquired as a part of the transfer of assets. Common causes include legislation or legal actions such as mergers or shifts in corporate structure.
- Name change: This occurs when an organization changes its name, but it doesn't affect the rights or obligations of the award recipient.

- Merger: This is when two or more entities legally unite. Handling of this scenario depends on its nature:
    - If the merger results in the transfer of awards, use the policies for a successor-in-interest.
    - If the merger doesn't involve award transfers, it's treated as a name change.

If the change would be considered a change of recipient organization as discussed above, then you must obtain prior approval.

For any change in organizational status, ask your GMS. This agency is usually the one that has granted you the most awards. The GMS can clarify whether the change will be treated as a name change or a successor-in-interest and guide you on the necessary steps to follow.

Financial Management

You must meet the standards and requirements for financial management systems in 45 CFR § 75.302. You must have adequate internal controls and a way to manage your award consistent with Department of the Treasury requirements. See the Payment section of GPS.

Financial management systems must:

- Provide accurate, current, and complete financial information about federal awards.
- Provide reasonable procedures to ensure that subaward recipients submit timely financial reports.
- Maintain records that:
    - Identify the sources of funds for award-assisted activities
    - Identify the award's purposes and uses, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income
    - Include accounting records supported by source documentation, such as canceled checks, paid bills, payrolls, and time and attendance records
    - Maintain effective control and accountability for all cash, property, and other assets under the award; adequately safeguard them; and ensure that they are used only for authorized purposes.
    - Compare actual expenditures with the approved budget amounts for the award.
    - Include written procedures to implement the requirements of 45 CFR § 75.305.
    - Include written procedures for determining the allowability of costs in accordance with 45 CFR part 75, subpart E.

Deficiencies in your financial management system may result in specific award conditions or increased monitoring.

States must expend and account for funds according to state laws and procedures for the state's own funds and ensure compliance with all the requirements above.

Payment

You accept an award and its terms and conditions by drawing down or requesting award funds from the designated HHS payment system or office.

HHS generally makes award payments through the Payment Management System (PMS). HHS grant payments are generally advance payments. You should draw down funds as often as needed.

In accordance with Department of Treasury regulations, you must draw federal cash only for your immediate needs. At time of draw down, you will certify you will not hold cash beyond three working days. You are responsible for knowing when funds are deposited into your bank account so that you can disburse them on time. You may end up with excess Federal cash on hand if you do not disburse or return funds on time. Do not request cash to cover unliquidated encumbrances, obligations, or accrued expenditures until payment is pending.

Refer to the Payment Management System (PMS) website and PMS User Guide | HHS PSC FMP Payment Management System for further guidance.

Types of Payment

As noted, HHS grant payments are generally advance payments. There are multiple ways to receive payments, including SMARTLINK II/ACH, CASHLINE/ACH, and cash request.

- SMARTLINK II/ACH: directly deposits funds to your bank account after you request them from PMS. You must have Internet access to submit a request for funds to PMS. This method makes funds available the day after the request using the Federal Reserve Bank's Automated Clearinghouse process.
- CASHLINE/ACH: directly deposits funds to your bank account using a telephone to call a "voice-response" computer at PMS. Makes funds available the day after the request with direct deposit using the Federal Reserve Bank's Automated Clearinghouse process.
- Cash request: provides payment if you are not eligible for unrestricted advance of funds. It will say in the NoA if you must use cash requests for payment. Cash requests may be an advance or reimbursement.

You may request funds monthly for advance payments. This request should be based on expected disbursements for following month and the amount of Federal funds already on hand.

A request for reimbursement may be submitted more often than monthly. You should submit requests to the awarding agency at least 2 weeks before the cash is needed. PMS makes payment electronically through the ACH process upon receipt of the approved payment request from the agency.

Refer to the Payment Management System (PMS) website and PMS User Guide | HHS PSC FMP Payment Management System for further guidance.

Interest Earned on Advances of Award Funds

You must keep advance payments in interest-bearing accounts, except as provided in 45 CFR § 75.305(b)(8). You can keep interest earned up to $500 per year for administrative expenses. Each year, you must remit any interest earned over $500 per year to the Payment Management System.

Indirect Costs

Indirect Cost Rate Negotiation and Salary Rate Limit (SRL) Policy

Please see Indirect Cost Rate Negotiation and SRL Policy in the Application Section.

New or Amended Indirect Costs

The GMO may permit new or increased indirect costs on an award when:

- A timely cost proposal was not received.
    - This can happen only if funds are available.
    - The amount is limited to the period after the effective date of the rate agreement.
- Rebudgeting changes a direct cost, which impacts an indirect cost.
    - The recipient may adjust the budget within the award ceiling and generally does need prior approval. See the Prior Approvals section of GPS.
- The indirect cost rate changes.
    - Generally, award amounts will not be adjusted based on a negotiated indirect cost rate different from that used at award.
    - However, if funds are available, a GMO may provide additional funds for indirect costs, only if:
        - An error was made in computing the award. This includes when a higher rate is negotiated after award and the date of the new rate agreement is within a month prior to the budget period start.
        - The awarding agency restores funds previously recaptured as part of an unobligated balance.
        - The recipient is eligible for additional indirect costs associated with additional direct costs awarded, such as a supplemental award.
        - A provisional rate was approved, and an approved indirect cost rate is now in effect.
    - The permanent rate will be used to determine indirect cost reimbursement, however:

- If the permanent rate is lower than the provisional rate, the award will not be adjusted downward, unless the indirect cost proposal included unallowable costs.
- The awarding agency is not required to provide new funds to accommodate a higher rate.

Applicable Credits

Applicable credits are funds saved or received that can reduce costs. Common examples include:

- Discounts
- Rebates
- Refunds for losses
- Corrections for overcharges

If you have any of these credits, you need to update the Federal Financial Report (FFR) to ensure that the proper amounts are charged to the award. If there are any extra steps, the awarding agency will let you know.

See 45 CFR § 75.406.

Allowable Costs and Activities

Allowable costs are either a direct cost or an indirect cost, and:

- Meet the applicable cost principles, including all the following:
  - Meet the factors affecting allowability. See 45 CFR § 75.403.
  - Are reasonable. See 45 CFR § 75.404.
  - Are allocable. See 45 CFR § 75.405.
  - Are allowable under the NOFO, program requirements, and NoA, including specific conditions and overall terms and conditions.
- Are specifically approved in the award, which means either:
  - The cost was included in the original award.
  - The cost is later approved by the awarding agency. See the Prior Approvals section of GPS.

Contact the GMS before incurring a cost if you have questions about allowability.

Subrecipients and contractors under the award must follow the requirements of their applicable cost principles.

Costs that Require Prior Approval

If you specifically describe a cost or activity that requires prior approval in your application budget, that cost is approved by the agency when you receive your award unless otherwise stated in the NoA. You do not need to get additional prior approval for that cost or activity.

You must get prior approval from the agency if you do not describe the cost or activity that requires prior approval in your application.

Profits and Fees

HHS will not provide profits or fees, except for the Small Innovation in Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.

You can't pay fees to subrecipients or consortium members, even if they are for-profit.

Contractors can make a profit for common goods or services in accordance with normal commercial practice. See 45 CFR § 75.351.

Expenditure Adjustments

Expenditure adjustments are used to correct accounting or bookkeeping errors. These adjustments move costs between two budget categories, with at least one related to the HHS award. Once the error is found, it must be corrected within 90 days. If after 90 days, you must ask the GMO for approval.

Don't use expenditure adjustments to cover cost overruns or for unallowable costs.

Documentation

The adjustment must be supported by documentation that fully explains how the error occurred. Documentation must:

- Explain how the error happened and have an official from your organization certify the correction.
- Show how the adjustment meets the cost principles of allowability, allocability, and reasonableness.
- Support why the adjustment is needed, considering the type of cost, the original charge, and when it was first recorded.

Unless the expenditure adjustment needs GMO approval, you don't need to send the documentation to the GMS. Keep records for monitoring or audits. See 45 CFR § 75.364.

Send a revised Federal Financial Report (FFR) if the adjustment changes your previous FFR.

Your financial system should catch errors quickly. Regular mistakes suggest you need to improve your accounting or internal controls. Agencies might ask for corrective actions or add terms and conditions to your award.

Rate of Expenditure and Drawdowns

Expenditure and drawdown rates give information about progress, financial management, and internal controls.

Expenditures

The GMS monitors spending rates within each budget period and throughout the period of performance.

The funds for each budget period are based on:

- the work planned for that time
- your budget, including any unobligated funds

HHS expects spending rates and types to match the approved plan and budget.

Drawdowns

The GMS checks drawdown patterns to see if money is taken out too early or too slowly. This can show:

- problems with your financial management system or internal controls
- risk of not finishing the project on time and within budget

If issues are found, the GMS will ask for more details and help you make corrections, which may include coordinating with the agency PO and GMS.

Cost Allocation

If a cost benefits more than one project or activity, divide the cost based on the benefit to each project.

If it is hard to determine the split because the projects are closely linked, distribute the costs on a reasonable basis with clear and documented explanations.

Treatment of Unobligated Balances

Unobligated balances are funds under an HHS award that you have not obligated. You calculate this by subtracting the cumulative amount of funds obligated from the cumulative amount of funds authorized.

Unliquidated obligations are commitments you have made, but not yet paid. Unliquidated obligations should not be reported as part of an unobligated balance.

If you have unobligated balances in your annual FFR, the awarding agency can:

- Carry Over: Revise the NoA to carry over to a following budget period.
- Offset: Move them to the next budget period but deduct the total from the award amount.
- A Mix: Use a mix of carry over and offset.

During an active budget period, if you have unobligated balances from a previous budget period, you can ask the awarding agency in writing to use them. If approved, the awarding agency will amend the NoA. If approved, funds carried over can be used for costs within scope of the project.

Program Income

Program income is gross income earned by an award recipient, subrecipient, or contractor and directly generated by an award-supported activity or earned as a result of the award.

Program income includes:

- fees for services
- charges for the use or rental of real property, equipment, or supplies bought with the award
- the sale of products made under an award
- charges for research resources
- license fees and royalties on patents and copyrights

The NoA governs the use of royalties and other income earned from a copyrighted work, patents, patent applications, trademarks, or inventions.

Accountability

Accountability refers to whether the awarding agency specifies how the program income is to be used, if the income needs to be reported to the awarding agency, and for what length of time. The following general policies apply:

- Unless otherwise specified in the award terms and conditions, you are not accountable for program income earned after the period of performance ends.
- Program income may be used only for allowable costs using the applicable cost principles and award terms and conditions.
- Subawards and contracts are subject to the same terms regarding generated income as the recipient. The following policies apply related to when the program income is earned:
    - Received and expended during the period of performance. Recipient is required to use program income as provided in the NoA.
    - Received and expended after the period of performance. Required to adjust the final FFR to reflect receipt and use of the income as directed by the GMO.
    - Received during the project period but expended after the period of performance. This may happen if you earn the income during the final budget period of the period of performance, please get GMO approval to use income post final budget period and adjust the final FFR accordingly.

Alternatives for Use

The NoA will tell you how to use program income. Here are the alternatives:

- Additive: Add it to the project's funds to further allowable objectives. Program income must be used for the purposes and under the conditions of the award.
- Deductive: Deduct it from the project's total costs and reduce federal funds and recipient cost-sharing contributions.
- Combination: Uses the additive alternative for program income up to $25,000 and the deductive alternative for any amount over $25,000.

- Matching: Use it as all or part of the non-federal (matching) part of an award.

See 45 CFR 75.307(e) for more information.

Generally:

- For non-research projects: If not specified in the NoA, use the deductive method.
- For research projects (except for awards to for-profit organizations other than the SBIR and STTR programs): If it is not specified, use the additive method.

Reporting of Program Income

Recipients must report the amount of net program income earned and expended on the FFR. This is the gross program income earned minus the costs associated with generating the income.

- Report program income using the additive alternative on line 10n, which will populate line 10o.
- Report program income using the deductive alternative on line 10m, which will populate line 10o.
- Report program income used to satisfy match on line 10j. Do not include it on line 10l.

Reporting requirements for accountable income earned after award support ends are in the NoA.

Cost Sharing

Cost sharing — or matching — is the portion of project costs not paid by federal funds, unless otherwise authorized by federal statute. This may include:

- The value of allowable third-party in-kind contributions.
- Non-award funded expenditures made by the recipient.

See 45 CFR § 75.306 for rules on cost sharing or matching.

The following policies apply:

- Cost sharing may be voluntary or required by the NoA.
- Required cost sharing is part of the total approved budget in the NoA. It is part of the award requirements and enforceable.
- Cost sharing must follow the same requirements as the federal portion of the budget. This includes applicable cost principles, prior approval requirements, and other rules for allowability.
- Recipients may apply program income toward cash match only when expressly permitted by the NoA with prior approval.
- All cost sharing contributions must be from allowable sources. See 45 CFR § 75.403, 45 CFR § 75.404 and 45 CFR § 75.405

- For research awards:
    - Voluntary cost sharing is not expected under research proposals.
    - Voluntary cost sharing cannot be used as a factor during merit review of research applications unless explicitly described in the NOFO review criteria.
    - Only mandatory cost sharing or cost sharing committed in the budget must be included in your research base for computing your indirect cost rate or reflected in allocating indirect costs.

The awarding agency will accept shared costs or matching funds, including cash and third-party in-kind contributions, when they meet all the following:

- follow 45 CFR § 75.306(e) for volunteer services
- are verified from the recipient records
- are necessary and reasonable to accomplish project objectives
- are provided for in the approved budget when required
- are not paid by the federal government under another federal award, unless specifically allowed by law. See 45 CFR § 75.306(b)(5)

The following policies apply:

- Sources of cost sharing or matching contributions must follow the applicable cost principles. See 45 CFR part 75, subpart E.
- If an awarding agency authorizes the recipient to donate buildings or land for construction or facility acquisition or long-term use, the value of the donated property for cost sharing or matching is generally the lesser of:
    - the value of the remaining life of the property recorded in the recipient's accounting records at the time of donation
    - the current fair market value

  See 45 CFR § 75.306(d).
- You must document in your records all costs and contributions used to satisfy a matching or cost-sharing requirement. These are subject to audit.
- You may use unrecovered indirect costs to satisfy cost sharing requirements with prior approval. These are the difference between the amount charged to the award and the amount that could have been charged to the award under the recipient's approved negotiated indirect cost rate.
- A third-party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing or matching requirement only if either:
    - it is an increase in the services or property provided under the contract without added cost to the recipient or subrecipient, or
    - it is a cost savings to the recipient or subrecipient.

If the NOFO specifies that matching or cost sharing is required, it will also say:

- Whether including matching or cost sharing in the application is an eligibility requirement or an evaluation criterion.
- The nature of the requirement. For example, whether it is a fixed percentage.
- Required documentation, like letters of commitment.

Valuation of Volunteer Services

Anyone offering skilled or manual work can volunteer for award-related activities. See 45 CFR § 75.306(e)-(f).

To value the services:

- For individuals:
  - Use the usual rates your organization pays or area market rates for similar work.
  - If you do not have a set rate, use the typical local rate for that work.
  - You can also add a fair amount for fringe benefits.
- For employees lent by other companies:
  - Use their regular rate if they are doing their typical job.
  - Use the method for individuals if they are doing something different.

Valuation of Donated Buildings and Land

If an awarding agency authorizes you to donate buildings or land for construction or facilities acquisition projects or long-term use, the value of the donated property for cost sharing must be the lesser of the following:

- the value of the remaining life of the property
- the current fair market value

See 45 CFR § 75.306(d), (h), and (i).

Enforcement

If you do not meet the specified level of cost sharing in the NoA, an awarding agency may do any or all of the following:

- reduce the award amount
- adjust down award funds during the budget period
- disallow costs post award

Procurement Management

You may acquire goods or services in support of award activities. The following policies apply when procuring property and services under an award:

- States must follow the same policies and procedures it uses for non-federal funds. Follow the requirements at 45 CFR § 75.326.
- All other recipients and subrecipients of a state must follow the procurement standards in 45 CFR §§ 75.327 through 75.335.

In order to procure goods and services, you must:

- Have written procurement procedures and standards of conduct that reflect applicable state, local, and tribal laws and regulations,
- Use a procurement method
- Do a cost or price analysis for all procurements above the simplified acquisition threshold
- Choose responsible contractors
- Follow all requirements in this section of the GPS

The HHS awarding agency has no direct relationship with your contractor.

Recipients other than federal institutions cannot use General Service Administration (GSA) supply sources except states who may acquire hardware and software from the GSA supply sources consistent with the terms and conditions of the GSA schedule.

Fixed Amount Subawards

With prior written approval from the GMO, you may provide subawards based on fixed amounts up to $500,000 (2 CFR § 200.333). Fixed amount subawards must meet the requirements for fixed amount awards in 45 CFR § 75.201.

Requirements for States

States may follow the same policies and procedures for procurements using non-federal funds. States will comply with 45 CFR § 75.331 and ensure that every purchase order or other contract includes any clauses required by 45 CFR § 75.335.

States may acquire hardware and software from Federal Supply Schedules consistent with the terms and conditions of the schedules.

State agencies or agencies that are political subdivisions of states must comply with section 6002 of the Solid Waste Disposal Act as amended by the Resource and Conservation Act. The requirements include:

- Procuring only items noted in guidelines of the Environmental Protection Agency (EPA) at 40 CFR § 247 that contain the highest practical percentage of recovered materials.
- Keeping an acceptable level of competition, where the purchase price of the item is more than $10,000 or the value of the amount acquired during the previous fiscal year was more than $10,000.
- Procuring solid waste management services to maximize energy and resource recovery.
- Establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

Requirements for Foreign Entities

The HHS awarding agency may require a review of all proposed procurements exceeding a certain dollar amount or for certain types of services. The HHS awarding agency may also add specific terms and conditions to its awards that address the procurement of such goods and services.

Selecting Responsible Contractors

You must avoid acquiring duplicate or unnecessary services or goods. You should use the most efficient strategy for acquisition. You should use federal excess and surplus property whenever possible to reduce project costs. You must award contracts based on factors like:

- Integrity
- Compliance with public policy
- Past performance
- Financial and technical resources

System for Award Management (SAM) Eligibility

You must check the System for Award Management (SAM.gov) to make sure that you do not make a subaward or contract to a debarred, suspended, or ineligible organization. SAM needs to be checked:

- By the recipient organization:
    - for all first tier subawards, regardless of the amount
    - for all first-tier procurement contracts of $25,000 or more
    - for all lower tiers of contracts under covered non-procurement transactions. See 2 CFR § 376.220.
- By the subaward recipient for all lower tier subaward recipients.

Written Agreements

You must execute a written agreement between your organization and the subrecipient, if applicable. The agreement must include all the following:

- the activities to be performed

- time schedule
- the provisions required by 45 CFR § 75.335 and found in 45 CFR part 75, Appendix II.
- policies and requirements that apply to the contractor, including 45 CFR § 75.327 and other relevant award terms and conditions
- maximum amount of funds to be awarded
- cost principles to be used in determining allowable costs for cost-type contracts

The following policy applies:

- The agreement must not affect your overall responsibility for the project or accountability to the federal government.

Subrecipient Periods of Performance - Contracts

If the term of the contract and the award budget period are not the same, you may charge the contract costs to the budget period in which the contract is executed even though some of the services will be performed in a later period. These conditions apply:

- You must notify the awarding agency.
- The expected contract performance period goes beyond the current budget period.
- You have a legal commitment to settle all contractual and administrative issues. See 45 CFR § 75.327(k).
- Only costs for services provided during the period of performance are allowable.
- For rental costs for facilities and equipment charge the applicable amount in each budget period as applicable. Contact the GMS before entering into leases that will result in direct charges to the award.

To limit liability, recipients should insert a clause in contracts less than $100,000 that states that payment after the end of the current budget period is contingent on continued federal funding.

Time and Materials Contracts

Time and materials contracts may only be used if:

- there is no other appropriate contract type
- the contract includes a ceiling price that the contractor exceeds at its own risk
- the direct hours are fixed and include wages, general and administrative expenses, and profit

Procurement Methods

You must use one of the following methods of procurement:

- Micro-purchases
- Small purchase procedures
- Sealed bids
- Competitive proposal

- Noncompetitive proposal

Micro-purchase procurements are the acquisition of supplies or services when the total dollar amount is less than the micro-purchase threshold ($50,000). To the extent possible, you must distribute micro-purchases equitably among qualified suppliers. Micro-purchases do not require soliciting competitive quotations if cost is reasonable.

Small purchase procurements involve simple procurement methods for securing services, supplies, or other property less than the Simplified Acquisition Threshold ($250,000). Non-federal entities must obtain price or rate quotes from sufficient qualified sources.

Sealed bid procurements require public solicitation for bids, leading to a firm fixed price contract (lump sum or unit price) given to the bidder whose bid is the lowest in price and complies with all material terms and conditions.

Competitive proposals usually involve more than one source sending an offer. A fixed price or cost-reimbursement type contract is awarded. It is generally used when sealed bids are not appropriate. You must adhere to the following requirements when using this procurement method:

- Requests for proposals must be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals must be considered to the maximum extent practical.
- Proposals must be solicited from an adequate number of qualified sources.
- You must have a written method for technical evaluations of the proposals and for selecting bids.
- Contracts must be awarded to the responsible firm whose proposal is best for the program.

You can also use the competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services. Applicant qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation.

Non-competitive proposals solicit a proposal from a single source. You may only use this method when the item is only available from a single source or in the event of a public emergency to expedite the acquisition, or when there is inadequate competition for a product, material, or service. You can get approval for non-competitive proposals from the GMO or his/her delegate.

Upon request, you are required to undergo a pre-procurement review and submit procurement documents to the HHS awarding agency or pass-through entity when:

- Your procurement procedures or operations do not comply with the procurement standards required by those regulations.
- The procurement is expected to exceed the Simplified Acquisition Threshold and is to be awarded without competition, or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the Simplified Acquisition Threshold specifies a “brand name” product.

- A proposed award over the Simplified Acquisition Threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.
- When prior written approval is required, the non-federal entity must make available sufficient information to enable review. This may include, at discretion, pre-solicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the non-federal entity or may be conditioned on the receipt of additional information. Any resulting approval does not constitute a legal endorsement of the business arrangement by the federal government nor does such approval establish the HHS awarding agency as a party to the contract or any of its provisions.

Written Standards of Conduct and Conflict of Interest

Recipients must maintain written standards of conduct covering conflicts of interest. Individuals affiliated with a recipient organization cannot participate in the selection, award, or administration of a contract supported by a federal award if they have a real or apparent conflict of interest with:

- Employees
- Officers
- Agents
- Immediate family members, spouses, or partners
- Potential employer

These individuals are prohibited from soliciting gratuities, favors, or anything of monetary value from subrecipients. However, recipients may set standards for situations where financial interest is not

agency for utilization using the SF-428-B (final) or SF-428-C (disposition). The recipient will receive disposal instructions from the HHS awarding agency.

Revocable License

In some cases, federally owned property may be made available to a recipient under what is called a "revocable license agreement." This agreement means the HHS awarding agency allows the recipient to use the property for the period of the award under the following conditions:

- The title to the property remains belongs to the federal government;
- The HHS awarding agency reserves the right to require the property to be returned to the should it be determined to be in the best interests of the federal government to do so;
- The use to which the non-federal entity puts the property does not permanently damage it for federal government use; and,
- The property is controlled and maintained in accordance with the requirements of the NoA.

Equipment

Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit purchase cost which equals or exceeds the lesser of the capitalization level established by the recipient for financial statement purposes, or $10,000.

Please see the general requirements under 45 CFR § 75.320 and 45 CFR § 75.439 for how to manage and track equipment. Unless a statute specifically says the recipient should own the title for equipment without further obligation to the HHS awarding agency, the title must be a conditional title. Under this conditional title, the recipient must:

- Use the equipment for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project; and,
- Not restrict the use of the equipment without approval of the HHS awarding agency.
- Subject to disposition instructions provided by the HHS awarding agency, use the equipment in the project it was acquired in as long as needed, whether or not the project continues to be supported by the federal award.

Important Property Reminders

- You must classify equipment that will be permanently attached or fixed to the land as real property.
- States must use, manage, and dispose of equipment acquired under a federal award by the state in accordance with state laws and procedures.
- Real property constructed or renovated with award support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by the awarding agency.

- If you default on a mortgage, you must immediately notify the GMS by telephone and in writing. If the mortgage holder intends to foreclose, you must notify the GMS in writing at least 30 days before the foreclosure action is initiated.
- The mortgage agreement must specifically allow, in the case of default, that HHS or its designee may assume the role of mortgagor (borrower) and continue to make payments.

Insurance

You must insure property and equipment acquired or improved under an award. The following policies apply:

- You must provide the same insurance coverage for property under an award as you do for other such property.
- You don't need to insure federally owned property unless required by the award terms and conditions.
- If your organization is a government agency, you may follow your own insurance requirements.
- If title to real property bought with award funds vests with your organization, you must provide the following minimum insurance coverage:
    - Title insurance policy covering the fee interest in the real property for an amount not less than the full appraised value of the property, even if federal support is partial.
    - Physical destruction insurance policy covering the full appraised value of the facility from risk of partial and total physical destruction, even if federal support is partial.
    - You must maintain the insurance policy for the duration of the federal interest in the property.

Within five days of completion or beneficial occupancy, you must submit a written statement signed by the AOR to the GMS. This statement must assure that you have purchased the required insurance policies and will maintain the insurance coverage as required above.

Self-Insurance

The awarding agency may waive one or both of the requirements above if you are effectively self-insured. If you claim self-insurance, you must provide the awarding agency an assurance that includes:

- A statement that you meet the definition of effectively self-insured. This means that you have sufficient funds to pay for any damage to the facility, including total replacement, or to satisfy any liens placed against the facility.
- The source of the funds, such as the organization's endowment or other special funds set aside for this purpose.

See 45 CFR § 75.447.

Notice of Federal Interest for Construction, Acquisition, and Modernization

A Notice of Federal Interest (NFI) is required for construction, acquisition, and modernization, except for Minor A&R. The non-federal entity (or owner, if other than the non-federal entity) must file an NFI prior to initiating construction or modernization, or when an existing facility or land is acquired with federal funds. The non-federal entity must:

- Record the NFI by the owner in the appropriate public records of the jurisdiction where the property is located. Associated fees are allowable costs.
- Provide a copy of the NFI to the HHS awarding agency.
- Accurately indicate that the property was constructed, acquired, or modernized with HHS awarding agency funds and, that during its useful life of the facility, as defined in the NFI, the HHS awarding agency's use and disposition requirements apply.
- Seek review by the HHS awarding agency to make sure it is acceptable.

The federal interest may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a non-federal entity unless approved by the HHS awarding agency.

Property and Equipment Disposition

According to 45 CFR § 75.318(c), you must request disposition instructions from the awarding agency when:

- Property under the award is no longer needed for the intended purpose or you will not be using the property for other activities currently or previously supported by an awarding agency.
- Federal statutes, regulations, or awarding agency disposition instructions in the NoA do not say otherwise.

Equipment

Unless the NoA or HHS awarding agency instructions say otherwise, you must dispose of the property as follows, in accordance with awarding agency disposition instructions:

- Retain, sell, or dispose of equipment items with a current fair market value of $10,000 or less, with no further responsibility to the government. See 2 CFR § 200.313(e)(1). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- Retain or sell equipment items with a current fair market value over $10,000. The following apply:
    - You pay the awarding agency the current fair market value according to the percentage of the federal share in its original cost.

- If sold, the awarding agency may allow you to deduct the lesser of $500 or ten percent of the proceeds from the federal share.
- If you organization is a non-profit institution of higher education or non-profit organization with a principal purpose of scientific research, you are exempt from any requirement to account for proceeds from a sale.

- Transfer property title to the federal government or an eligible third party. You are entitled to compensation for its share of the current fair market value.

Supplies

Your organization is assigned the title to supplies when you acquire them. If you have more than $10,000 in supplies after the award is terminated or project is completed, you must retain the supplies for use on other activities, or sell them, and then compensate the federal government for its share. See 2 CFR §200.314.

Modernization of Real Property

Modernization includes both major and minor alterations and renovations (A&R) unless otherwise stated. Modernization is not an allowable cost under the following:

- Federal awards to individuals
- Conference awards

You may not perform major A&R using federal funds or required matching or cost sharing unless

- There is specific statutory authority, and
- The NoA explicitly allows it.

Minor A&R is an allowable cost under all types of awards with prior approval under the following criteria, unless restricted in the NOFO or NoA:

- The governing statute or program regulations do not exclude it.
- The work is required to use the space more effectively to meet the program needs.
- The building has a useful life consistent with the project and is architecturally and structurally suitable for conversion.
    - If you own the property, it has a useful life consistent with the project.
    - If you lease the property, the terms and length of your lease are consistent with the project.
- Work and costs to get an initial occupancy permit is not an allowable cost. Costs must be for purposes other than human occupancy (e.g., storage).
- If the building is under construction or the A&R will take place in an incomplete structure, the costs are only allowable if:
    - It is cost-effective to perform the A&R while the building is under construction or being completed, and

  - Minor A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting it for the federal award supported purpose.

- The space involved will be occupied by the project.
- National Environmental Policy Act (NEPA) and the National Historic Preservation Act (NHPA) requirements are followed, as applicable.

The following are not considered minor A&R:

- Costs associated with routine maintenance, painting, and repair of facilities or equipment that are normal business costs and generally charged as indirect.
- Certain costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, unless the non-federal entity's accounting system considers these modernization costs rather than equipment costs.
- Costs of furnishings and movable equipment.

Federal Interest Involving Construction and Modernization of Leased Property

You must make sure any leased property that you propose construction or modernization costs for has a long enough lease for the full value of the federal award supported improvements to benefit the award activity and support the expected useful life of the facility. You must submit additional documentation to the HHS awarding agency in these cases:

- You must submit lease language to the HHS awarding agency prior to drawing down funds or being reimbursed.
- The property owner must consent to the proposed work, acknowledge federal interest in the property, and file a Notice of Federal Interest (NFI), if required. The lease must include, or be amended to include:

  - Your full use of and access to the leased property during the term of the lease.
  - Your agreement not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-federal award-related purpose(s) without the written approval of the HHS awarding agency (at any time during the term of the lease, whether or not federal award support has ended).
  - That the lessor will inform the HHS awarding agency of any default by the non-federal entity under the lease.
  - The HHS awarding agency has 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period.

- The HHS awarding agency intervening to ensure that the default is eliminated by the non-federal entity or another non-federal entity named by the HHS awarding agency.
- The lessor accepting payment of money or performance of any other obligation by the HHS awarding agency's designee, for the non-federal entity, as if such payment of money or performance had been made by the non-federal entity.
- If the non-federal entity defaults, the federal award is terminated, or the non-federal entity vacates the leasehold before the end of the lease term, the HHS awarding agency has the right to designate a replacement for the non-federal entity for the balance of the lease term, subject to approval by the lessor in a separate agreement with HHS, which will not be withheld except for good reason.
- Documentation of a NFI for the leased property (if required).

Intangible Property

Intangible property is property having no physical existence. These may include:

- trademarks, copyrights, patents, and patent applications
- property, such as loans, notes, and other debt instruments; lease agreements; stock; and other instruments of property ownership

Intellectual Property

HHS expects you and your PIs and PDs to make your award results and accomplishments available to the research community and the public. If the research results in inventions, the Bayh-Dole Act of 1980 and 37 CFR part 401 apply. If you follow these requirements, you have the right to retain title to any invention conceived or first actually reduced to practice.

The law and regulation promote:

- commercialization of federally funded inventions.
- free competition and enterprise without restricting future research and discovery.

The law and regulation require recipients to:

- Make efforts to develop and commercialize the technology to advance to industry for development.
- Make unpatented research products or resources available through licensing to vendors or other investigators.
- Share copyright-protected research outcomes in journal articles or other publications.

Irrevocable and Royalty-Free License

Except as otherwise provided in the NoA, you may assert copyright in any publications, data, or other copyright-protected work developed under an award. Doing so does not require awarding agency approval.

Rights in data also extend to students, fellows, or trainees under awards with an educational purpose. In this case, authors are free to assert copyright in works.

The federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use material resulting from a supported project or program. This applies whether HHS funded all or part of the project. You are responsible for ensuring that any necessary copyrights obtained from your subrecipients also allow the material to be used by the federal government.

HHS may also extend this license to others for federal purposes. For example, to make it available in government-sponsored databases for use by other researchers. The NoA addresses the specific scope of awarding agency rights. See 45 CFR § 75.322(d), 45 CFR § 75.365.

Access to Research Data

A federal agency may use award-related research data in developing an agency action that has the force and effect of law. If so, 45 CFR § 75.322(e)(1) requires recipients to release the research data to the awarding agency to support a FOIA request. See 45 CFR § 75.322(e). See also:

- the definition of research data at 45 CFR § 75.322(e)(3).
- the definition of records, which includes research data at 45 CFR § 5.3.

Excluded are:

- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects (e.g., laboratory samples, audio or video tapes)
- trade secrets
- commercial information
- materials necessary to be held confidential by a researcher until publications in a peer-reviewed journal
- information that is protected under the law such as intellectual property
- personnel, medical files, and similar files, if disclosure would constitute an unwarranted invasion of personal privacy
- information that could be used to identify a particular person in a research study

If the data are publicly available, HHS directs the requester to the public source. Otherwise, the awarding agency FOIA coordinator handles the request, consulting with the recipient and the PI. The recipient may charge a reasonable fee to cover their costs to respond. HHS may do the same.

This requirement to release research data does not apply to for-profit organizations or to research data produced by state or local governments. However, if a state or local government recipient contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to disclosure.

Patents and Inventions

Inventions conceived or first actually reduced to practice under awards are governed by the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR part 401.

The regulations at 37 CFR § 401 apply if both the following are true:

- Inventions result from federally funded research.
- Your organization or your subrecipient or contractor is a university, non-profit entity, governmental entity, or small or large business.

See iEdison for more information.

Royalties and Licensing Fees from Copyrights, Inventions, and Patents

You may commercially apply intellectual property and require payments for its use.

Unless the NoA says otherwise, you do not have to report program income earned from license fees and royalties. This includes copyright-protected material, patents, patent applications, trademarks, and inventions made under an award.

You may pay royalties to others as an allowable direct cost.

See 45 CFR § 75.448.

Invention Reporting

For information, see Invention Reports at iEdison. See also 37 CFR part 401.

Seek the advice of the GMS about:

- Whether an invention made under a career development award is a subject invention
- The extramural technology transfer policy
- Reporting of inventions

Publications and Acknowledgement of Support

Publications

HHS encourages you to publish the results and accomplishments of awards. You can publish your results without prior approval. These policies apply, unless otherwise specifically addressed in your NoA:

- You may assert copyright in scientific and technical articles based on data produced under the award.

- You may transfer copyright to the publisher or others for journal publication or other professional activities.
- All copyrights, including transfers, are subject to a royalty-free, non-exclusive and irrevocable license to the federal government, and any agreement must include that the assignment is subject to the government license.
- You must account for royalties and income earned from a copyrighted work as specified by the awarding agency.
- You must submit one copy of each publication resulting from work under an award with the annual or final progress report.
- If you plan to issue a press release about award-supported activities, you must notify the awarding agency in advance to allow for coordination.

Stevens Amendment

HHS will include the following information in your NoA and NOFO. When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as toolkits, resource guides, websites, and presentations – describing the projects or programs funded in whole or in part with HHS funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

The NoA may provide further instructions and language to use.

Acknowledgement of Support

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as tool-kits, resource guides, websites, and presentations (hereafter "statements") – describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

- If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources: This [project/publication/program/website, etc.] [is/was] supported by the [full name of the OPDIV/STAFFDIV] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX

with 100 percent funded by [OPDIV/STAFFDIV]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Name of the Awarding Agency]/HHS], or the U.S. Government. For more information, please visit [Award Agency Stevens Amendment website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

- This [project/publication/program/website, etc.] [is/was] supported by the [full name of the HHS Awarding Agency] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with XX percentage funded by [full name of the HHS Awarding Agency]/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Awarding Agency]/HHS, or the U.S. Government. For more information, please visit [Award Agency's Stevens Amendment website, if available].

Oversight and Monitoring

Subrecipient Flow-Down Requirements

The GPS applies to subrecipients and contractors. This includes consortium agreements where the recipient collaborates with other organizations.

The terms and conditions of awards flow down to subawards and subrecipients unless a particular GPS policy or award term and condition specifically says otherwise.

You have to have a formal written agreement with each subaward recipient. You must include applicable GPS requirements in your subaward agreements. Agreements must meet programmatic, administrative, financial, and reporting requirements. At a minimum, the subaward agreement must include:

- the PI or PD and subrecipient staff responsible for the program activity, including roles and responsibilities
- program administration and monitoring procedures
- policies and process for subrecipient funding, such as allowable costs, expenditure approval, funding caps, payment method and schedule, required documentation
- travel, salaries, and fringe benefit policies and procedures
- applicable public policy requirements and applicable assurances and certifications and provisions indicating the intent of the subrecipient to comply, including submission of applicable assurances and certifications
- conflict of interest requirement
- provisions regarding property, program income, publications, reporting, record retention, and audit

Reporting

You must submit financial, performance, and other reports. Not meeting reporting requirements could result in enforcement actions. These actions include those in the Remedies for Noncompliance section of the GPS including 45 CFR §§ 75.371-.380, and reporting to Responsibility/Qualification in SAM.gov (formerly FAPIIS).

Federal Financial Reports

You submit Federal Financial Reports (FFRs) through the Payment Management System (PMS).

How often you need to submit an FFR is in the NoA. This can range from quarterly to annually. Higher risk recipients may report more often.

Updated information on FFRs is at the Program Support Center for PMS.

You may need to revise your FFR in some cases. You must submit a revised FFR to HHS immediately for overcharges. You also must submit revised FFRs as soon as possible for expenditures that you did not report before. You must explain why the revision is necessary and how you will prevent this in the future. For annual FFRs, revisions are due no later than 9 months from the end date. For final FFRs, revisions are due no later than 6 months after the end date. The agency will tell you how your award will be updated if revised FFRs are accepted.

PLEASE NOTE: The GMS may not accept a revised interim FFR submitted by the recipient that claims additional expenditures after one year from the end of the reporting period (regardless of when the original report was actually submitted).

Progress Reports

You submit progress reports through GrantSolutions or NIH eRA.

The reporting schedule and requirements are in the NoA. Schedules can range from quarterly to annually. Higher risk recipients may report more often.

See 45 CFR § 75.342(b)(1).

Other Reporting

Intellectual Property Reporting

If you have a research award, you must report on patents and inventions through iEdison (iEdison | NIST).

Each competing continuation application and progress report (when used in lieu of a non-competing continuation application) must indicate whether or not any subject inventions were made during the preceding budget period.

Invention Reporting

You must report on inventions. The iEdison website includes information on invention reports. See also 37 CFR part 401.

You must also submit an annual invention use report for:

- all inventions to which title has been elected, and
- inventions that have been licensed but not patented (research tools).

The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

Contact the GMS for questions, including:

- if inventions under a career development award is a subject invention
- the extramural technology transfer policy
- reporting and use of inventions

Real Property Reporting

Construction awards must report the status of real property each year for as long as the federal government retains an interest, up to 15 years. If the federal interest lasts beyond 15 years, the awarding agency or pass-through entity may require the recipient to report at various multi-year frequencies.

Non-Compliance

Failure to Submit Reports

When you fail to submit required reports within the time allowed, the awarding agency may take enforcement actions including those in the Remedies for Noncompliance section of the GPS.

Overdue Reports

An awarding agency may give a waiver, if permitted by law, or extension if a report is overdue and the reason is beyond your control.

Failure to meet a new date may result in the awarding agency taking enforcement actions.

Submission of a required report does not necessarily fulfill your obligation. Reports must meet content requirements. You must provide the revised report by the indicated due date to avoid enforcement actions.

Fraud, Waste, and Abuse

Fraud, waste, or abuse related to HHS awards or use of award funds should be reported to HHS. Fraud, waste, and abuse may be reported:

- By telephone at 1-800- HHS-TIPS (1-800-447-8477) or TTY at 1-800-377-4950
- Fax at 1-800-223-8164. Forms for use are available at the OIG website.
- E-mail at HHSTips@oig.hhs.gov
- USPS mail at U.S. Department of Health and Human Services, Office of Inspector General, Attn: OIG Hotline Operations, P.O. Box 23489, Washington, DC 20026.

If you report, you are not required to give your name, but if you do, your identity is kept confidential.

Fraud, waste, and abuse includes embezzlement, misuse or misappropriation of award funds or property, and false statements or claims. Examples include:

- theft of award funds for personal use
- using funds for non-award-related purposes
- theft of federally owned property or property acquired or leased under an award
- charging inflated building rental fees for a building owned by the recipient
- submitting false financial report
- submitting false financial data in bids submitted to the recipient

The federal government may pursue administrative, civil, or criminal action under a variety of statutes that relate to fraud and false statements or claims. Even if no award is made, you may be subject to penalties if information submitted as part of an application is found to be false, fictitious, or fraudulent. See the statutes referenced in Appendix D and Appendix E for statutes related to fraud, waste, and abuse.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 USC 35, as implemented by 5 CFR part 1320, is designed to:

- Reduce, minimize, and control burdens
- Maximize the practical use and public benefit of the information created, collected, disclosed, maintained, used, shared, and disseminated by or for the federal government

OMB clearance is required for awarding agency collection of information. This includes all application or reporting forms, whether paper or electronic. Below is information about how the PRA is implemented.

Federally Sponsored Surveys

Recipients may use award funds to collect information through surveys or questionnaires:

- When the collection of information is not a primary objective of the award but is incidental to, or is an integral part of, an award-supported activity
- When the collection of information is a primary objective of the award, but such information is not intended primarily for use by the federal government, or a party designated by the federal government

When information is collected, according to either of the two conditions above, you may not represent what the information is being collected for, or in association with, unless:

- You receive awarding agency approval, and
- You follow OMB report clearance procedures, when required. When OMB approval is required, the awarding agency, rather than the recipient, will obtain the necessary clearance.

OMB clearance is required whenever the HHS awarding agency sponsors the use of a reporting form or plans to collect identical kinds of information or data from 10 or more people.

Information collection is considered HHS awarding agency-sponsored when any of the following circumstances exist:

- The awarding agency allows you to state that the information is being collected for, or in association with, the awarding agency.
- You use the report form or collect information that an awarding agency has requested for the planning, operation, or evaluation of its program.
- The award terms and conditions provide awarding agency approval of the study design, questionnaire content, or data collection procedure.
- The award terms and conditions provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the awarding agency.

HHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted privacy invasion.

Collection of the following types of information is not subject to the clearance requirements at 5 CFR § 1320:

- health professions data as described in Section 708 of the Public Health Service (PHS) Act
- tests or examinations of individuals for determining knowledge, abilities, or aptitudes, and the collection of information for identification or classification in connection with such tests
- information from patients to be used exclusively for research of or direct treatment of a clinical disorder; for the interpretation of biological analyses of body fluids, tissues, or other specimens; or for identification or classification of such specimens

See 5 CFR § 1320 for additional clearance requirement exemptions.

Remedies for Noncompliance

If you do not comply with award terms and conditions, the awarding agency or pass-through entity may take enforcement actions, in accordance with applicable statutes, regulations and policy.

You usually have an opportunity to correct the deficiencies unless there is a serious threat to public health or welfare concerns. The awarding agency may take necessary proactive steps to protect the federal government's interests. Awarding agencies may take any action allowed by law, including those below. See 45 CFR §§ 75.371-.380.

Implementation of Specific Award Conditions

An awarding agency or pass-through entity may place specific conditions on an award. The purpose is corrective. This remedy may be used if you:

- fail to comply with the terms and conditions of an award
- fail to meet expected performance goals

- are not otherwise responsible

When the awarding agency or pass-through entity imposes specific award conditions, they will notify you of:

- the nature of the conditions
- the reason why
- the type of corrective action needed
- the time allowed for completing corrective actions
- the method for requesting reconsideration of the conditions

Examples of specific award conditions are removing a PD/PI, converting your award from advance payment to reimbursement, and adding reporting requirements.

See 45 CFR § 75.207.

Disallowed Costs

HHS may disallow all or part of the cost of an activity or action determined not in compliance. This can happen at any time during the award or after closeout.

You must repay disallowed costs with non-federal funds or an offset from future year funds. You may appeal disallowed costs.

Other Remedies

Depending on the nature of the deficiency, an awarding agency also may:

- temporarily withhold payment
- withhold further awards for the project or program

Suspending Award Activities or Termination

Consistent with 45 CFR § 75.372(a), an awarding agency or pass-through entity may suspend, pending corrective action, or terminate all or part of your award activities pending your corrective action if you fail to materially comply with the award terms and conditions. See 45 CFR part 75 D – Remedies for Noncompliance.

The HHS awarding agency generally will suspend, rather than immediately terminate, a federal award. This allows you an opportunity to take appropriate corrective action before making the decision to terminate. The HHS awarding agency may decide to terminate the federal award if you do not take appropriate corrective action during the period of suspension.

Under a suspension, the HHS awarding agency will provide you:

- What project activities, if any, will take place during the period of suspension.
- What costs the HHS awarding agency will reimburse if the enforcement action is ultimately lifted and the award resumed.
- What corrective actions must occur during the enforcement action.

- The HHS awarding agency's intent to terminate the award if the non-federal entity does not meet the conditions of the enforcement action.

The HHS awarding agency may terminate without first suspending the federal award if the problem is serious enough or if public health or welfare concerns require immediate action. Termination for cause may be appealed under the HHS awarding agency and HHS's federal award appeals procedures.

A federal award also may be terminated, in whole or partially, by the recipient or by the HHS awarding agency with the consent of the recipient. If you decide to terminate a portion of a federal award, the HHS awarding agency may determine that the remaining portion will not accomplish the original purpose. In this case, you will be advised of the possibility of termination of the entire federal award and will be allowed to withdraw your termination request. If you do not withdraw your request for partial termination, the HHS awarding agency may terminate the entire federal award for cause. See 45 CFR § 75.372.

When an HHS awarding agency terminates a federal award prior to the end of the period of performance due to the non-federal entity's material failure to comply with the federal award terms and conditions, the HHS awarding agency must report the termination to the OMB-designated integrity and performance system accessible through the Responsibility/Qualification System in Sam.gov. This information will be reported after the non-federal entity has exhausted its opportunities to object or challenge the decision or has not within 30 calendar days after being notified of the termination informed the HHS awarding agency that it intends to appeal the decision to terminate. For full information on reporting termination in FAPIIS, see 45 CFR § 75.372(b).

HHS applies appeal rights in line with 45 CFR § 75.374. Appeals rights exist for termination actions that are a remedy for non-compliance.

Suspension or Debarment

An awarding agency may initiate suspension or debarment proceedings under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376. A pass-through entity may recommend that the awarding agency do so for a subaward.

Closeout

To close an award, you do several steps to include submitting a final report. Ask your GMS and review the closeout provisions HHS now follows at 2 CFR § 200.344. The awarding agency will resolve any amounts due to them or to you.

Upon the completion date of an award, you have 120 days to liquidate all financial obligations and submit all required reports, including a final FFR, final progress report, tangible and real property reports (if needed), and Final Invention Statement and Certification (if needed). The GMO or their delegate may give an extension upon a written request. Not submitting timely and accurate reports can affect future funding. HHS may close out your award on its own if you fail to provide your reports on time.

HHS may still disallow costs or recover funds based on an audit or review after your award is closed out. After closeout, you still have to return any funds due to HHS because of refunds, corrections, indirect cost rate adjustments, or other transactions.

You still need to account for property acquired on your award and follow disposition and record retention requirements after close out. HHS adopted two 2 CFR § 200 provisions about equipment and salary disposition:

- 2 CFR § 200.313(e) - Equipment: Increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency." The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- 2 CFR § 200.314(a) - Unused Supplies: Increases from $5,000 to $10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items.

See 45 CFR §§ 75.317-323 for other disposition requirements. See 45 CFR §§ 75.361-75.365 for record retention requirements. Keep in mind the above changes in equipment and supply costs adopted by HHS in 2 CFR § 200.

Final Federal Financial Report (FFR)

A final FFR is required for all of the following:

- terminated awards
- awards transferred to new recipients
- awards at the end of a period of performance

Final FFRs must:

- account for all funds awarded during the period of performance
- have no unliquidated obligations
- say the exact unobligated balance

In some cases, you may need to submit a revised FFR. When a revised final FFR results in additional recipient claims, the awarding agency will consider approval if:

- You show why the revision is needed, explains, and implements internal controls to avoid similar future situations
- The charge is allowable under the award
- There is an unobligated balance for the budget period that can cover the claim
- The funds are still available

- The awarding agency receives the revised FSR within 6 months of its original due date

Final Progress Report

A final progress report is required for all of the following:

- terminated awards
- awards at the end of the performance period

Submit final progress reports as directed in your NoA.

Use the awarding agency instructions. At a minimum, they include:

- a summary of progress towards achieving the stated aims
- significant results, positive or negative
- publications

If you submit a competing continuation application, the final progress report requirement may be met by the information included in that application.

Final Invention Statement

For research awards, you must submit a Final Invention Statement and Certification (HHS 568). HHS requires this statement even if the award does not result in any inventions. The HHS 568 is at the iEdison Web site at iEdison | NIST.

The HHS 568 lists all inventions conceived or initially reduced to practice under the award. The form must be signed by the PI or PD and AOR. The form covers the period from the original award start date through the award end date. If there were no inventions, the form should indicate "None."

Post-Closeout

After award closeout, you still have obligations for record retention, property accountability, and financial accountability. See 45 CFR §§ 75.317-.323 and 75.343.)

Record Retention and Access

You must keep financial, supporting, and statistical records, and all other records considered pertinent to an award.

The retention periods are three years after sending:

- the final FFR for closed awards
- quarterly or annual reports for awards renewed quarterly or annually

These periods are extended until the conclusion of any litigation matters, claims, or audits and audit findings are fully resolved.

You must allow records access to the:

- HHS Awarding Agency
- Inspector General
- Comptroller General
- Pass-through Agency

See:

- Retention requirements for records (45 CFR § 75.361)
- Access to records (45 CFR § 75.364)
- Restrictions on public access to records (45 CFR § 75.365)

Debt Collection

During or after closeout, HHS may find that you received more than the correct amount or that you misspent funds. This may result from disallowed costs, recovery of funds, unobligated balances, or other situations. In these cases, HHS will send you a request for repayment. Debts to HHS agencies are considered delinquent 30 days after you are notified. You have 90 calendar days to repay the amount.

If you do not pay back the funds in 90 calendar days, the HHS awarding agency may reduce your debt by:

- making an administrative offset against payments on other HHS awards
- withholding advance payments
- taking other action allowed by law

HHS must, by law, collect debts due to the federal government. Unless prohibited by law, HHS is also required to charge interest on delinquent debts.

See Collection of Amounts Due (45 CFR § 75.391) for more.

You may appeal a request for repayment. If appealed, HHS suspends the collection pending a final appeal decision. If denied, in whole or in part, HHS will charge interest on the debt starting with the date of the original request for repayment.

Refer to the HHS Claims Collection (45 CFR part 30) and the Program Support Center's Debt Management Collection System at https://pms.psc.gov/ for more on collection of debts.

Appeals

Awarding agencies may have their own appeals procedures. See also the procedures of the Departmental Appeals Board (45 CFR part 16).

Awarding agencies and recipients may use alternative dispute resolution (ADR). ADR can reduce the cost, time, and level of dispute involved in appeals.

For more information on appeals, see Opportunities to Object, Hearings, and Appeals (45 CFR § 75.374) and the Departmental Appeals Board website.

Single Audit

An audit is a review to verify if accounting and control systems reasonably assure:

- proper financial operations
- timely, fair, and correct financial reports
- compliance with applicable laws, regulations, and terms and conditions of award
- resources are managed and used economically and efficiently
- desired results and objectives are being achieved effective
- recipients and subrecipients follow the audit requirements of 45 CFR part 75, subpart F.

Audit Requirements

As of October 1, 2024, you and your subrecipients must have an audit if either spends $1,000,000 or more in federal awards during its fiscal year (see 2 CFR § 200.501). Even if an audit is not required, keep records available for review by federal officials.

You must use an independent auditor who must follow the Government Auditing Standards and the audit requirements in 45 CFR 75, subpart F. Audit costs are allowable and often covered by the indirect cost rate.

Pass-through entities are responsible for establishing audit requirements, to ensure compliance by subrecipients.

HHS may request more audits, if necessary.

Types of Audits

Program Specific Audit**:** test a single program. Refer to 45 CFR § 75.507.

- Single Audit: The auditor uses a risk-based approach to identify major programs which the auditor tests and provides an opinion on compliance. See 45 CFR part 75, subpart F.
- Financial Related Audit: Specific to for-profit organizations. Must be conducted in accordance with the Government Auditing Standards.

Audit Options

If an audit is required, the following options are available:

For Governments, Indian Tribes, Institutions of Higher Education, and Non-Profits

- Only one program: If federal awards are expended in only one program, the program-specific audit is an option.
- Multiple programs: If federal awards are expended from more than one program, a single audit is required.

For-Profit Organizations

- Only one program: If federal awards are in only one program, then they may opt for a program-specific audit or financial related audit of the award.
- Multiple programs: If federal awards are in more than one program, then they must have a single audit or financial related audit of all awards.

Contractors

Audit requirements for federal awards do not apply to contractors with annual HHS awards less than $1,000,000. See 2 CFR § 200.501.

Foreign Entities

Audit requirements and processes for foreign entities will be addressed in your NOFO and NoA.

Recipient Responsibilities

- Procure or otherwise arrange for the required audit and make sure it is performed properly. See 45 CFR § 75.509.
- Provide the auditor with access to needed personnel, accounts, books, records, supporting documentation, and other information.
- Prepare financial statements, including the schedule of federal award expenditures. See 45 CFR § 75.510.
- Make sure the audit is submitted within 9 months after your fiscal year end. See 45 CFR § 75.512.
- Promptly follow up and take corrective action on audit findings.

See 45 CFR § 75.508 for a listing of auditee responsibilities.

Audit Findings and Resolution

Non-Federal entities and their subrecipients must follow up and take corrective action on all audit findings. This includes preparing:

- a summary schedule of prior audit findings. See 45 CFR § 75.511(b).
- a corrective action plan. See 45 CFR § 75.511(c).

Requirements

The summary schedule and the corrective action plan must include:

- reference numbers the auditor assigns to audit findings under 45 CFR § 75.516(c)
- the fiscal year in which the finding initially happened
- findings relating to the financial statements required to be reported under Government Auditing Standards

See 45 CFR § 75.511.

Report Submission

Reports for non-profit recipients are submitted to the Federal Audit Clearinghouse (FAC). For-profit and foreign recipients submit reports to ARD or the Centers for Disease Control (CDC) (if CDC is the awarding agency).

The HHS assignment system receives single audit reports from the FAC and assigns audit findings to the awarding agencies for resolution.

Both you and your auditors must complete and submit your portions of the reporting package to FAC. They are due within 30 calendar days after receipt of the auditor's report or nine months after the end of the auditee's fiscal year.

See 45 CFR § 75.512.

Delinquent Audits

HHS will follow up to obtain audit reports that are delinquent.

If required audits are not completed or do not follow 2 CFR part 200 and 45 CFR part 75, audit costs may be disallowed or other sanctions may be taken.

HHS Office of Inspector General

The HHS Office of Inspector General (OIG) audits programs and their recipients to ensure funds are used correctly and guard against fraud and waste. The OIG:

- can freely access records and information
- can request information and documents through subpoenas
- acts as the National Single Audit Coordinator, giving audit guidance to HHS agencies and recipients

You need to have strong internal controls and guidelines must be in place to ensure proper use of federal funds.

Documentation

Ensure that the basis for valuing services, materials, equipment, buildings, and land can be verified. Make sure your records, including those from your subrecipients, can support the value. If using volunteer services, document their time and attendance as you would for regular employees.

Additional Information

Cooperative Audit Resolution and Management Decisions

Cooperative audit resolution is a structured approach that brings the appropriate stakeholders together to address audit findings and proposed corrective actions. Non-federal entities must follow this approach to ensuring timely and appropriate resolution of audit findings and recommendations. The non-federal entity must initiate and proceed with corrective action as quickly as possible and corrective action should begin no later than upon receipt of the audit report.

The HHS awarding agency will coordinate with the non-federal entity during the cooperative audit resolution process. The HHS awarding agency will:

- Follow-up on audit findings to ensure the non-federal entity takes appropriate and timely corrective action.
- Issue a management decision, on all assigned reporting packages with audit findings within six months of the date the FAC accepts the reporting package.
- Issue sanctions when the non-federal entity fails to correct conditions identified by audits that are likely to cause improper payments, fraud, waste or abuse.

The HHS awarding agency or pass-through entity responsible for issuing a management decision must do so within 6 months of acceptance of the audit report by the FAC. The management decision provides timely information to the non-federal entity regarding where the HHS awarding agency is in evaluating findings and related corrective actions. The HHS awarding agency management decision will include:

- whether or not the audit finding is sustained
- the reasons for the decision
- the expected action the non-federal entity must take to repay disallowed costs, make financial adjustments, or take other action
- a timetable for follow-up if then non-federal entity has not completed corrective action
- a description of the appeal process available to the non-federal entity

Appendix A: Awarding Agencies Overview

Below is an overview of HHS awarding agencies. Visit HHS Organization Chart | HHS.gov for more.

GPS refers to "Public Health Service (PHS) agencies." We have marked them below.

Agency	Overview	Support
Administration for Children and Families (ACF) www.acf.hhs.gov	Promotes economic and social well-being of children, families, and communities.	• childcare for low-income families • foster care and adoption • child abuse and domestic violence prevention
Administration for Community Living (ACL) www.acl.gov	Advocates for older adults, people with disabilities, families, and caregivers to help all people live independently and participate in their communities.	• health, wellness, and nutrition • self-advocacy • connecting people to services • retirement planning • American Indian, Alaska Native, and Native Hawaiian nutrition and older adult support
Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov PHS agency	Improves quality, safety, accessibility, equitability, and affordability of US health care.	• digital healthcare research • PSNet (Patient Safety Network) • quality indicators
Administration for Strategic Preparedness and Response (ASPR) www.aspr.hhs.gov	Assists the country in preparing for, responding to, and recovering from public health emergencies and disasters.	• development and stockpiling of medical countermeasures • pandemic preparedness
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) www.healthit.gov	Administers health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve health care.	• advance development and use of health IT capabilities • establish expectations for data sharing
Centers for Disease Control and Prevention (CDC) www.cdc.gov PHS Agency	Protects against health and public health, safety, and security threats. Their focus is both foreign and domestic.	• immunization services • monitoring and preventing disease outbreaks • disease prevention strategies • workplace safety

Centers for Medicare & Medicaid Services (CMS) www.cms.gov	Advances health equity, expanding coverage, and improving health outcomes.	• clinical standards and quality • minority health equity • meaningful measures
Food and Drug Administration (FDA) www.fda.gov FDA Grants and Cooperative Agreements Page PHS Agency	Protects public health by ensuring the safety of human and veterinary drugs, biological products, medical devices, cosmetics, and food.	• food safety • animal feed safety • laboratory systems • scientific conferences
Health Resources and Services Administration (HRSA) www.hrsa.gov PHS Agency	Provides access to essential health care services for people who are low-income, uninsured, or live in areas with limited access.	• rural health • maternal and child health • opioid response • health workforce training • telehealth
Indian Health Service (IHS) www.ihs.gov PHS Agency	Ensures comprehensive, culturally appropriate personal and public health services are available to American Indians and Alaska Native people.	• community health • behavioral health • environmental stability • school health
National Institutes of Health (NIH) grants.nih.gov PHS Agency	Seeks knowledge about the nature and behavior of living systems. Applies it to enhance health, lengthen life, and reduce illness and disability.	• biomedical and behavioral research • research training • research infrastructure and communications
Office of the Assistant Secretary (OASH) www.hhs.gov/ash PHS Agency	Seeks to serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures.	• minority health • family planning • adolescent health • women's health • infectious disease and HIV/AIDS policy • research integrity
Office of the Inspector General (OIG) www.oig.hhs.gov	At the forefront of the Nation's efforts to fight waste, fraud and abuse and to improving the efficiency of Medicare, Medicaid and more than 100 other Department of Health & Human Services (HHS) programs.	• Medicare/Medicaid oversight • improved efficiency • fraud, waste, abuse detection

Substance Abuse and Mental Health Services Administration (SAMHSA) www.samhsa.gov PHS Agency	Improves the quality and availability of substance abuse prevention, addiction treatment, and mental health services.	• substance abuse and mental health services.

For awarding agency staff and recipient roles and responsibilities, see the Introduction and General Information section.

Appendix B: Abbreviations and Glossary

Abbreviations

Please see abbreviations listed in 45 CFR part 75. The abbreviations are used by the HHS Financial Assistance Community. Although not all of the terms are in the GPS, they may be useful to applicants and recipients.

Glossary

This glossary defines terms commonly used in the HHS GPS. These definitions are for purposes of clarity and do not replace controlling definitions in applicable statutes and regulations.

acquisition cost	The total invoice price of items, counting costs for changes or accessories or additions to make them work for their intended use. Costs like setup, shipping, taxes, and insurance can be included or excluded based on the recipient's usual accounting methods. The term doesn't cover rental or property modification costs.45 CFR § 75.2 Acquisition cost
accrual basis	Accrual accounting records revenue and expenses when the transaction happens, not when money is paid.
administrative requirements	Common practices in managing awards like financial accountability, reporting, equipment management, and records retention.
advance payment	A payment made to a recipient before they spend the money or based on set payment schedules. 45 CFR § 75.2 Advance payment
allocable cost	An allocable cost relates to a specific project or activity based on the relative benefits it provides. It's allocable to a federal award if: • It's specifically for the award. • It benefits both the award and other tasks, and can be distributed based on those benefits. • It's needed for the organization's overall functioning. 45 CFR § 75.405 Allocable costs
allowable cost	Allowable costs are: • Reasonable for the award's purpose. • Allocable. • Within the federal cost principles or NoA guidelines. • In line with the recipient's consistent policies, covering both federal and non-federal activities. • Consistently treated as either a direct or indirect cost. • Based on standard accounting principles. • Not used in another federal award, unless statute says otherwise. 45 CFR § 75.403 Factors affecting allowability of costs

alteration and renovation (A&R)	Alteration and renovation involve changing the inside or features of a facility or installed equipment to enhance its current use or adapt it for a new purpose. It can include improvements, remodeling, or modernization but is different from construction or major permanent upgrades.
alternative dispute resolution (ADR)	A method to solve disagreements without going to court. It aims to resolve issues faster, cheaper, and in a less confrontational way, preventing them from becoming bigger problems that need formal legal action.
applicable credit	Receipts that offset or reduce direct or indirect costs. Typical examples include purchase discounts, rebates, or allowances; recoveries or indemnities on losses; insurance refunds; and adjustments of overpayments or erroneous charges. 45 CFR § 75.406 Applicable credits
application	A request for financial support of a project or activity submitted on specified forms and in accordance with awarding agency instructions. See Types of Applications.
approved budget	The spending plan for a project funded by an award. This budget has both federal funds and, if applicable, non-federal funds like cost-sharing. If both types of funds are in the budget, the recipient must spend them in the same ratio as they appear in the total budget. See also 45 CFR § 75.2 Budget
assurance	A written statement by an applicant, normally included with the application, that it will follow a particular requirement if there is an award.
audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings like questioned costs. See also 45 § CFR 75.2 Cooperative audit resolution.
award	The document that provides the awarding agency funds to a recipient to carry out an approved project, based on an approved application. In the GPS, award means both grants and cooperative agreements. 45 CFR 75.2 Federal award
awarding agency	The agency responsible for making, monitoring, and overseeing awards. For changes in award terms or for approval requests, the reference may be to the GMS. See also 45 § CFR 75.2 Federal agency.
award-supported project	Activities described in an application or in a subsequent submission that are approved by an awarding agency for funding, even if federal money isn't the sole financial support for them.
award terms and conditions	The legal requirements set by the awarding agency for the award. These can come from laws, regulations, policies, or the NoA. The NoA might also add specific conditions to ensure the award's goals are met, enable post-award management, save funds, or protect federal interests.
budget periods	The period of time (usually 12 months each) into which a period of performance is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as “incremental funding.”

carryover	Unspent federal funds from a particular budget period that can be transferred and used in the next budget period used to cover allowable expenses in that subsequent period. Funds that have been committed but not yet spent (obligated but unliquidated) are not classified under carryover.
cash basis	An accounting method in which revenue and expenses are recorded on the books of account when received and paid, respectively, without regard to the period in which they are earned or incurred. It is different than accrual basis.
change of recipient	Transfer of the legal and administrative responsibility for an award from one legal entity to another before the end of the period of performance.
closeout	The process used by an awarding agency to determine whether all administrative actions and work required under the award have been completed by the recipient and the awarding agency. 2 CFR § 200.344
cognizant agency	The federal agency that, on behalf of all federal agencies, reviews, negotiates, and approves cost allocation plans, indirect cost rates, and similar rates. They monitor non-federal audit reports; conduct federal audits as necessary; and resolve cross-cutting audit findings. The cognizant agency under applicable cost principles and under 45 CFR part 75, subpart F may be different for a given recipient. 45 CFR § 75.2 Cognizant agency for indirect costs
competition	A process in which applications undergo a merit review and are evaluated against established evaluation criteria in the NOFO.
completion date	The date on which all work under an award is completed or the date in the NoA (as amended) on which federal sponsorship ends (i.e., the end of a period of performance).
consortium agreement	A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards.
contract under an award	A written agreement between a recipient and a third party to acquire commercial goods or services. 45 CFR § 75.2 Contract
construction	A project to support the initial building or major alteration and renovation like large-scale modernization or permanent improvement of a facility.
consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. Also includes a firm that provides paid professional advice or services.
cooperative agreement	A financial assistance support mechanism used when there will be substantial federal programmatic involvement. Substantial involvement means that the awarding agency's program staff will collaborate or participate in project or program activities as specified in the NoA. 45 CFR § 75.2 Cooperative agreement

copyright	Protection provided by statute (Title 17, U.S. Code) to the authors of "original works of authorship," including literary, dramatic, musical, artistic, and certain other intellectual works, including computer programs. This protection applies to both published and unpublished works.
cost analysis	The systematic review of a budget proposal to: • Detail and assess cost components. • Ensure costs are necessary, reasonable, and allocable. • Confirm alignment with federal guidelines, ensuring no unallowable expenses.
cost sharing	See "matching or cost sharing."
Departmental Appeals Board	The DAB is a board within HHS that impartially addresses disputes from HHS assistance programs. It offers a fair hearing process for challenges to certain grants management decisions, with its role and rules outlined in 45 CFR part 16. 45 CFR § 75.2 Departmental Appeals Board
direct costs	Costs directly linked to a specific project, instructional activity, or other institutional activities, which can be accurately and easily allocated to those activities. 45 CFR § 75.413 Direct costs
domestic organization	A U.S.-based public or private entity, subject to U.S. laws, responsible for the legal and financial management of awarded funds and the execution of the supported activities.
Entity Identification Number (EIN)	A 12-character code in PMS comprising three parts: the first character indicates if the recipient is an organization or individual; the following 9 characters represent the TIN for organizations or the SSN for individuals; the final 2 characters differentiate between organizational entities with the same or multiple EINs, denoting subsidiaries, branches, or other subdivisions.
equipment	A tangible item with a lifespan exceeding 1 year and a cost of $5,000 or more per unit, or below the recipient's capitalization threshold, whichever is lower. 2 CFR § 200.1 Equipment
excess property	Property that, as decided by the head of the awarding agency or its representative, is no longer needed for the agency's functions or responsibilities. 45 CFR § 75.2 Excess property
exempt property	Tangible personal property bought either entirely or partly with federal funds, where the awarding agency has the legal authority to vest title to the recipient without additional obligations to the federal government. 45 CFR § 75.319 Federally owned and exempt property
expanded authorities	Permissions granted to recipients that eliminate the need for prior approval from the awarding agency for certain activities.
expiration date	The specified date in the NoA marking the conclusion of the current budget period, beyond which the recipient is not authorized to obligate award funds.

facilities and administrative costs (F&A)	See indirect costs
federal institution	A Cabinet-level department or independent agency within the executive branch of the federal government, or any of its sub-entities.
federal share	The proportion, usually expressed as a percentage of the total project costs, that represents the financial and other direct contributions provided by the awarding agency, as detailed in the NoA. 45 CFR § 75.2 Federal share
fee	A sum paid beyond the actual allowable costs to an entity delivering goods or services in line with standard commercial practice, often referred to as "profit."
financial assistance	The provision of funds, property in place of funds, or other direct aid to a qualified recipient to encourage or further a public purpose authorized by law.
foreign component	The execution of a major part or component of a project outside the United States by the recipient or by a researcher affiliated with a foreign institution, regardless of whether award funds are used.
foreign organization	An entity situated in a country outside of the United States and its territories, governed by the laws of that nation, regardless of the nationality of the proposed Principal Investigator/Project Director. 45 CFR § 75.2 Foreign organization
for-profit organization	A legal entity formed for the purpose of generating profit for its shareholders or owners. This type of organization is also known as a "commercial organization." See also 45 § CFR 75.2 Commercial organization.
grant	A funding mechanism given to an eligible entity to support a public-purpose project or activity without significant involvement from the awarding agency. Unlike direct benefits for the government, a grant provides financial assistance or other resources to accomplish approved objectives. See also 45 § CFR 75.2 Grant agreement.
high risk	A recipient with a history of subpar performance, financial instability, or inadequate management, placing them at risk of financial or operational failure.
human subject	An individual from whom an investigator collects data via intervention, interaction, or acquisition of identifiable private information, including organs, tissues, body fluids, or any related graphic or recorded details. Regulations govern the use of human subjects.
Indian tribal government	The governing body overseeing an Indian tribe, group, or community, including Alaska Native villages per the Alaska Native Claims Settlement Act of 1971. This body is recognized by the Secretary of the Interior for access to specific programs and services via the Bureau of Indian Affairs and the Indian Health Service. See also 45 CFR § 75.2 Indian tribe.

indirect costs	Costs incurred by a recipient for shared purposes and not tied to a specific project or program. They are also referred to as "facilities and administrative costs." 45 CFR § 75.2 Indirect (Facilities and Administration or F&A) costs
institutional review board (IRB)	A committee that safeguards the rights and well-being of human subjects in research. The IRB can approve, modify, or disapprove research activities under its jurisdiction.
intangible property	Property without physical form, such as copyrights, patents, and other intellectual property rights acquired under awards. It also encompasses loans, notes, leases, stocks, and other ownership instruments. However, intellectual property created, rather than purchased, under awards is excluded.45 CFR § 75.2 Intangible property
international organization	An organization with members from multiple countries, representing their interests, regardless of whether its headquarters or activities are located within or outside of the US.
invention	A potentially patentable or protectable discovery or invention made by an awardee during work funded by a contract, grant, or cooperative agreement. The term "subject invention" refers to inventions specifically conceived or first reduced to practice as part of the funded work.
key personnel	The PI/PD and other individuals who contribute to the programmatic development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award.
local government	A local government entity such as a county, city, town, township, school district, or council of governments, among others. This includes regional or interstate government entities and local public authorities, but excludes institutions of higher education and hospitals. 45 CFR § 75.2 Local government
matching or cost sharing	The value of non-federal contributions to a federally assisted project, including third-party in-kind donations. These costs must adhere to the same allowability policies as other costs in the approved budget. 45 CFR § 75.2 Cost sharing or matching
merit review	An unbiased evaluation of discretionary applications by experts in the relevant field. Also known as objective review. See also 45 CFR § 75.204 HHS funding agency review of merit of proposals.
monitoring	A method of evaluating an award's programmatic and business management performance using data from reports, audits, site visits, and other sources.
non-competing extension	An additional timeframe beyond the original period of performance, granted by the awarding agency or recipient (under expanded authority), to finalize project activities.
non-federal share	The portion of allowable project costs not borne by the Federal government.
notice of funding opportunity (NOFO)	An official announcement from the awarding agency that outlines the availability of federal funds for a specific program. This announcement invites applications and provides essential details such as eligibility requirements, evaluation criteria, and guidelines for application preparation and submission.
objective review	See merit review.

obligations	The value of commitments made by a recipient during a budget period for orders, contracts, subawards, and received goods and services, that will need payment within the current or later budget periods. 45 CFR § 75.2 Obligations
outlays or expenditures	The charges made to the federally sponsored project or program. They may be reported on a cash or accrual basis. 45 CFR § 75.2 Expenditures
patent	A property right awarded by the federal government that grants the right to exclude others from making, using, or selling the invention for a period of years.
peer review	A method of evaluating the merit of applications based on assessment by individuals of equal scientific or technical expertise (peers). This review ensures that applications meet high scientific or technical standards, as determined by experts in the relevant field.
period of performance	The total time for which support of a project has been programmatically approved. 45 CFR § 75.2 Period of performance
pre-award costs	Costs incurred before the official start date of an award, expected to be covered by the award but undertaken at the applicant's own risk, given there's no guarantee of reimbursement unless later approved. 45 CFR § 75.209 Pre-award costs
prior approval	Written approval from the awarding agency's CGMO, or their delegate, granted in response to a recipient's request, to incur a specific cost or action requiring such approval. If these costs/actions are detailed in an application, the award's issuance based on that application serves as the authorization. For indirect cost components, prior approval must come from the relevant agency or as per the associated cost principles. 45 CFR § 75.2 Prior approval
profit	See fee
program income	Income directly produced by a project, program, or activity funded by the award, or earned due to the award. 45 CFR § 75.2 Program income
progress report	Regularly submitted reports, typically annually, from the recipient to the awarding agency to evaluate progress and determine funding for the next budget period, excluding the final report.
real property	Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment. 45 CFR § 75.2 Real property
recipient	The entity or individual awarded a grant or cooperative agreement by the awarding agency. They are accountable for the funds and the execution of the project or activity. Even if a specific component is mentioned in the NoA, the recipient refers to the complete legal entity. 45 CFR § 75.2 Recipient
reimbursement	A payment made to a recipient upon its request after it makes cash disbursements.

research	A comprehensive study aimed at expanding knowledge or addressing a specific need. It involves the application of knowledge to produce materials, devices, systems, or methods, including the design and enhancement of prototypes and processes. Often referred to as "research and development." 45 CFR § 75.2 Research 45 CFR § 75.2 Research and Development (R&D)
research patient care	Standard and supplementary hospital services given to research participants. The expenses for these services are typically allocated to individual research projects using established research patient care rates.
subaward	Financial assistance given as money or property under an award by a recipient to a qualified subrecipient (or by a subrecipient to a lower-tier subrecipient). This aid can be provided through any legal agreement, even if termed a contract, but excludes procurement of goods/services or any assistance other than grants and cooperative agreements. Consortium agreements are included. 45 CFR § 75.2 Subaward
subrecipient	An entity that receives a subaward from a recipient or another subrecipient under a financial assistance award and is responsible to that recipient or subrecipient for the proper use of the federal funds provided by the subaward. 45 CFR § 75.2 Subrecipient
substantive programmatic work	The primary project activities for which award support is provided.
supplies	Tangible items that are not classified as equipment, intangible property, or debt instruments. While some items in the "supplies" category might resemble equipment, they don't meet the specific criteria or cost threshold to be categorized as such. 2 CFR § 200.2 Supplies
suspending award activities	A temporary halt on a recipient's ability to use award funds until they take corrective action as directed by the awarding agency or until the agency decides to end the award. This definition of "suspension" is distinct from its use in the context of debarment and suspension procedures. 45 CFR § 75.2 Suspension of award activities
tangible personal property	Tangible assets including equipment and supplies, excluding intangible property like intellectual property.
termination	The awarding agency's permanent removal of a recipient's right to commit previously granted funds before the initial authority ends, which can include the recipient willingly giving up that right. 45 CFR § 75.2 Termination
total project costs	The total allowable costs (both direct and indirect) that the recipient incurs to carry out a project supported by the award. This includes costs billed to the award itself and costs that the recipient covers as part of a matching or cost-sharing agreement. 45 CFR § 75.2 Total Costs

unallowable cost	A cost specified by law or regulation, federal cost principles, or term and condition of award that may not be reimbursed under a grant or cooperative agreement.
unliquidated financial obligations	If using a cash basis, the amount of obligations made by the recipient that have yet to be paid. If using an accrual basis, the sum of obligations made by the recipient for which a disbursement or expense hasn't been recorded. 45 CFR § 75.2 Unliquidated obligations
unobligated balance	The amount of the funds authorized by the federal agency that the recipient has not obligated. 45 CFR § 75.2 Unobligated balance
vertebrate animal	Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or related purposes.
withholding cash payment	The awarding agency, after following necessary steps, limits a recipient's access to funds until they make the needed corrections.

Appendix C: Post-Award Considerations by Type of Program, Activity, or Recipient

Services Provided by Affiliated Organizations

Universities and other organizations (parent organizations) sometimes create affiliated organizations.

The parent organization often provides considerable support services. These include administration, facilities, equipment, accounting, and other services. The affiliated organization includes the costs of these services in its indirect cost proposal.

In some cases, the awarding agency may reimburse these costs. This happens only when the affiliated organization satisfies any of the following:

- It is charged for, and must legally pay for, the costs.
- It is subject to state or local law that sets out how to spend the federal reimbursement and a state or local official approves the expenditures.
- A formal agreement allows the affiliated organization to keep the related federal reimbursement. The parent organization may direct the expenditure of the funds or allow the affiliated organization to decide.

If these conditions don't apply, the awarding agency cannot reimburse the costs. However, the services may be acceptable for cost-sharing purposes.

Data Sharing for Research and Demonstration Projects Considerations

Expectations

Sharing data and research tools is important to quickly turn research into useful products and knowledge to improve human health. This includes things like cell lines and software. Also sharing information about demonstration projects helps others use and duplicate projects. If you are an NIH recipient, reminder to please go to the NIH GPS at:
https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

HHS encourages researchers to share their findings promptly.

If you enter into subawards, including consortium agreements, and you want access to third-party data or research tools, include a provision in the third-party agreement. There may be times the HHS awarding agency requires you to do so They can also access third-party data or tools. Please check the NoA.

You must also share copies or samples of materials developed under the award. You can charge a small fee for shipping and handling these items. Any income earned from this is considered program income.

If you think you can't meet these expectations, talk to the GMS before getting an award.

Timely Release of Research Data and Tools

Investigators should share their final research data and tools either when their main findings are accepted for publication or when they submit findings to the awarding agency. This ensures timely sharing.

Protection of Certain Data

HHS knows data sharing can be complicated due to various rules and laws, including the HIPAA Privacy Rule, Human Research Protections, and others. We must always protect the privacy of project participants and their data.

For wider use, data must not include any indicators that could reveal the identity of individual participants. Researchers need to ensure that data from human cells or tissues also can't reveal the identity of the original donors.

Researchers can share materials through their lab or organization or submit them to a repository. They should send unique biological data, like DNA sequences, to the appropriate data banks. When sharing unique resources, investigators must provide details about the nature, quality, or characterization of the materials.

Conference Awards

If you have questions about conference awards or what's allowed under your award, ask your GMS.

Here are definitions and details about costs related to conference awards:

- Conference: Events like meetings, retreats, or seminars that share technical information. They must be necessary and reasonable for the award's success.
- International conference: A meeting open to attendees from at least two countries other than the U.S. or Canada. It can be anywhere, even in the U.S. But, if it's outside the U.S. or Canada, award funds can't cover general support. They can cover specific parts, like a workshop or panel.
- Domestic conference: A meeting in the U.S. or Canada mainly for attendees from these two countries. Award funds can support these conferences, whether they're domestic or international.

Equity in Representation

For HHS-supported meetings, ensure diverse participation. Recipients of HHS financial assistance awards must make sure all those eligible for the HHS funded project are able to participate and receive the benefits from the project. When administering HHS-funded meetings, programs, activities, projects, assistance, and services, the recipient must make sure no one able to participate is discriminated against, to the extent doing so is prohibited by Federal statute. Please see 45 CFR § 75.300 and Advancing Equity at HHS for more information.

Funding Requirements

The NoA will include any specific requirements. A change in conference focus is a change in scope and needs prior approval.

Acknowledgment of Support and Disclaimer

All conference materials, like agendas or media promotions, must mention HHS support, whether in whole or in part. Refer to Appendix D for the exact wording of this acknowledgment.

If you're releasing a press statement about activities supported by an HHS award, inform the awarding agency beforehand to coordinate, which may include a review of mate

Allowable and Unallowable Costs and Activities

Please refer to 45 CFR part 75, subpart E, your NOFO/NoA, and the HHS awarding agency.

Other Cost Considerations

If you don't have a written travel policy, follow the Federal Travel Regulation. Always adhere to the U.S. foreign travel restrictions in place at the time, which may include restrictions on countries or limits on funds for travel.

When attending a conference:

- Only claim per diem for days you attend and the actual travel time, taking the most direct route.
- Local travel costs can be covered for local attendees only.
- If meals or lodging cost are nominal or free, like within a registration fee, adjust your per diem accordingly.
- Travel costs shouldn't exceed coach fares. Always choose U.S. carriers when possible.

Intellectual Property: Publications, Copyright, and Public Disclosure

If you publish something using HHS funds, you can distribute it for free. If you sell it, the money earned is considered program income and should be reported as directed in your NoA and on the FFR. More details can be found in the Program Income section of the GPS Program section After the Award.

You can seek copyright for publications from an HHS-supported conference unless your award says otherwise. However, HHS still has rights to the materials, as mentioned in the Irrevocable and the Royalty-Free License GPS section After the Award.

Construction and Modernization of Facilities Awards

Applicability and Definitions

Note that construction and modernization activities must be allowed by law; that law may provide more specifics about allowable construction and modernization activities. However, as a general matter, this section applies to the following HHS award-supported activities:

- Construction: constructing a new building, structure, or facility that provides new space. It also includes installing fixed equipment in such space. It excludes purchasing land and ancillary improvements like parking lots, roads, or fencing. Constructing shell space is not allowed as a construction activity as it does not provide usable space.
- Modernization: altering, renovating, remodeling, improving, expanding, or repairing an existing building. Also includes completing existing shell space. Activities must make the building suitable for the purposes of a particular program. This can include space used for storage or by people. It can range from updating flooring to replacing everything except for the existing frame and foundations. If the main award purpose is modernizing a biomedical research facility, the award can't also support research.
- Alteration and renovation (A&R) activities: These are modernization activities and can be under research awards where the primary purpose of the award is other than construction or modernization.

Refer to the NoA for additional related requirements.

Allowable and Unallowable Costs and Activities

This section outlines costs and activities generally allowable and unallowable under construction awards. (The final decision is based on the decision of the HHS awarding agency and the program.)

These policies apply to the use of federal funds and cost sharing or matching funds. The lists are not all-inclusive. Consult program guidelines and award terms and conditions for specific costs allowable under a program or award.

Allowable Costs and Activities

- Acquisition and installation of fixed equipment.
- Architectural and engineering services.
- Bid advertising.
- Bid guarantees and performance and payment bonds as provided in 45 CFR § 75.334.
- Contingency funds for unanticipated charges included in the initial cost estimates for construction contracts. Before you receive bids, the budgeted amount can't exceed five percent of expected construction costs. You must reduce it to not more than two percent after you award a construction contract.
- Filing fees for recording the Notice of Federal Interest (NFI).
- Force accounts to provide funding for your own construction and maintenance staff used in carrying out modernization activities. These are allowable if you can document that a force account is less expensive than if you were to competitively bid the work. You must substantiate costs with receipts for the materials and certified labor pay records. Use of a force account requires awarding agency prior approval.

- Compliance with the National Historic Preservation Act. This can include:
- hiring special consultants to research and document the historic value of proposed performance sites
- costs to prepare and present required materials to inform the public and others.
- Incentive costs for contractors consistent with contract type as specified in the solicitation of bids or proposals and in the contract. Incentive costs must be reasonable and documented, including that conditions to earn the incentive were met. Incentive-type contracts may also contain a penalty provision. Other types of bonus payments are not allowable.
- Inspection fees.
- Insurance costs of title insurance, physical-destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs. However, you can treat it as a direct cost if your established policy does so and you consistently do so. You may charge title insurance, if required, to the award in proportion to the amount of awarding agency participation in the property. See Real Property —Insurance.
- Legal fees related to obtaining a legal opinion about title to a site.
- Relocation expenses.
- Sidewalks necessary for use of facility.
- Site clearance costs are allowable if reflected in the bid.
- Site survey and soil investigation costs.
- NEPA analysis costs to evaluate the environmental effects and produce the Environmental Impact Statement (EIS).
- Pre-award costs for architect and consultant fees needed for planning and design are allowable if the project is later approved and funded.
- Project management costs.
- Threat-risk assessment costs for a site-specific or project-specific assessment of security risk by a qualified professional. The threat-risk assessment identifies and quantifies potential threats, both internal and external to the building, its contents, the personnel working in it, and the general public. The analysis also includes examination and evaluation of the physical aspects of the proposed facility, along with operational issues.

Unallowable Costs and Activities

- Bonus payments other than earned incentive payments to contractors under formal incentive arrangements.
- Construction of shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract.

- Indirect/F&A costs.
- Fund-raising expenses.
- Land acquisition.
- Legal services not related to site acquisition.
- Movable equipment.
- Off-site improvements such as parking lots.

Prior-Approval Requirements

You must get awarding agency prior approval for the following types of project or budget changes:

- Any applicable changes as specified in the Prior Approvals section of the GPS.
- Change in the use of the facility. See Use of Facility and Disposition in this section.

You must provide enough details in your approval request to explain why you need the change. Once approved, you can make the changes. For smaller changes to construction contracts, you don't need prior approval. But keep copies of all changes as part of your award records.

Procurement Requirements

Construction activity usually is conducted through one or more contracts. All such procurement must use the methods described in 45 CFR §§ 75.327 through 75.335, as applicable.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

You must provide equal employment opportunity and labor standards requirements for federally assisted construction and modernization to potential bidders/offerors and include them in the resulting contract. See 45 CFR part 75, Appendix II (C) and 41 CFR chapter 60. The Davis-Bacon Act or the Copeland "Anti- Kickback" Act apply only if specifically required by the program's authorizing statute. The NoA will show if they apply.

Equal Employment Opportunity Requirements

Construction contracts (and subcontracts) awarded under HHS awards must follow the requirements of EO 11246 and implemented in 41 CFR § 60-1. Recipients must:

- Include the "Equal Opportunity Clause" at 41 CFR § 60-1.4(b) in any construction contract under the award. You must direct the contractor to include this clause in any applicable subcontracts.
- Follow solicitation and contract requirements for affirmative action specified in 41 CFR § 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in EO 11246.
- Notify the Office of Federal Contract Compliance Programs regional, area, or field office when you expect to award a construction contract over $10,000.

Labor Standards Requirements

- Under EO 13202, as amended by EO 13208, you must ensure that bid specifications, project agreements, or other controlling documents for construction services contracts:
- Ensure that bidders, offerors, contractors, or subcontractors are able and willing to enter into or adhere to agreements with one or more labor organizations on the same or other related construction projects.
- Refrain from discrimination against bidders, offerors, contractors, or subcontractors for initiating, refusing to initiate, or adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Under 41 CFR § 60-1.8, segregated facilities are not permitted for any contract for construction services that will exceed $10,000. The recipient must require each prospective contractor to submit a certification that the contractor:

- Maintains all facilities provided to employees in a non-segregated manner
- Prohibits its employees to perform services at any location, under the contractor's control, that maintains segregated facilities
- Obtains a similar certification before awarding any covered subcontract

Awards, contractors, and subcontractors with construction contracts or subcontracts over $100,000 must follow the Contract Work Hours and Safety Standards Act, 40 USC 3701–3708. Among other provisions, the statute covers standards listed below. Consult the statute for proper interpretation and guidance.

- Work hours
- Report of violations and withholding of amounts for unpaid wages and liquidated damages
- Health and safety standards in building trades and construction industry
- Safety programs
- Limitations, variations, tolerances, and exemptions
- Contractor certification or contract clause in acquisition of commercial items not required
- Criminal penalties

Other Requirements

Liquidated Damages

Invitations for bids must supply a date or timeframe to complete the project for each prime contract. You may include a liquidated damages provision in the contract. It allows you to assess damages when the contractor does not complete the construction or modernization by the specified date. Liquidated damages must be real, justified, and approved by the awarding agency before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

Disposition of Unclaimed Wages

If an employee doesn't claim wages from an HHS-supported construction contract, the recipient might need to pay HHS back. Here's the process:

- Check that the contractor tried to find the employee. This might include forwarding mail or contacting their union.
- If the contractor's search fails but seems incomplete, try to find the employee.
- Open an escrow account in the employee's name. Keep it for two years after the contract ends, or longer if local laws say so. Tell the GMS about this account.
- If you pay wages from the account to the employee or their representative, report to the GMS when you close the account.
- If money is still unclaimed after two years, refund the awarding agency based on the award's contribution to those wages.

Use of Facility and Disposition

Unless a statute or instructions from your awarding agency say otherwise, here's how to manage real property:

- Keep using the property for its intended purpose. Don't sell or encumber the title without approval.
- If you don't need it for the initial purpose, get written approval from the awarding agency to use it for a similar federally funded project.
- If you no longer need the property, follow the rules in 45 CFR 75.318. Your options include:
- Keep it and pay the awarding agency their fair share based on their contribution and the property's market value.
- Replace it. If buying new property under the same award, use any sales money to reduce the new property's cost.
- Sell it and pay the awarding agency based on a formula in 45 CFR 75.318(c)(2).
- Transfer it to the awarding agency or their approved third party. They'll pay you your fair share based on your contribution and the property's current market value.

Foreign Organizations, International Organizations, and Domestic Recipients with Foreign Components

The GPS generally applies to awards to foreign organizations and international organizations. You can find the definitions of these terms in Appendix B of the GPS. In this section, we refer to them as foreign awards.

The AOR must contact the GMS if their organization can’t follow these requirements. This section includes:

- Exceptions and modifications to GPS requirements for foreign awards
- Highlights of other related policies
- Policies that apply to awards with a foreign component

Public Policy Requirements and Objectives

Requirements in Appendix D apply to foreign awards, unless otherwise noted here, the NoA, or in awarding agency policies. Exceptions include:

- Civil rights: The civil rights requirements do not apply to foreign awards.
- Debarment and suspension: These rules and the certification requirement do not apply to:
- foreign governments and foreign recipients
- public international organizations
- entities that are foreign-government-owned or controlled, in whole or in part

All other foreign organizations and international organizations are subject to these rules.

- Drug-Free workplace: The awarding agency may exempt foreign awards from these requirements. To do so, they must find that the requirements are not consistent with U.S. international obligations or the laws and regulations of a foreign government.
- Environmental requirements: A foreign award isn't subject to environmental requirements that would not otherwise apply to it.

Funding and Payment

These policies apply:

- All application budgets, fund requests, and financial reports must be in U.S. dollars.
- If exchange rates change, extra costs might be covered, depending on the awarding agency's available funds.
- You only need prior approval for rate changes if they lead to needing more federal funds or if they will reduce project scope significantly.
- Review local currency gains to determine if you will need additional federal funding before the award ends.
- Adjustments for currency increases may be allowable only when you provide the awarding agency with adequate source documentation from a commonly used source in effect at the time you made the expense.

Allowable and Unallowable Costs

The cost principles that apply to foreign organizations depend on the type of organization. See Cost Principles. There are some exceptions:

- Major A&R are unallowable under foreign awards and domestic awards with foreign components, except where allowed by the governing statute and as indicated in the NoA.
- Minor A&R are generally allowable on awards made to foreign organizations or to a foreign component of a domestic award, unless prohibited by the governing statute or implementing program regulations. You may include and justify minor A&R costs in the detailed application budget. Rebudgeting to accommodate minor A&R requires prior approval.
- F&A Costs under foreign awards, including foreign recipients with a domestic component, are at a fixed rate of eight percent of modified total direct costs. These are direct costs minus tuition and related fees, equipment, and subawards in excess of $25,000. See 45 CFR 75.414(c)(1)(ii). These funds are to support the costs of compliance with federal requirements.
- Capital expenses (facilities) are not allowable, except where allowed by the governing statute and as indicated in the NoA. The awarding agency will not support the acquisition cost or provide for depreciation.
- Equipment is an allowable direct cost.
- Patient care costs are provided only in exceptional circumstances or where allowed by the statue setting up the award program.
- Travel Visas (including short-term) are generally allowable:
    - As a direct cost as part of recruiting costs if the institution has an employee-employer relationship with the individual
    - When identified in specific NOFOs
    - If within the scope of an approved research project

Administrative Requirements

Expanded authorities generally apply to foreign awards. Review the NoA to determine the specific award requirements. See the Prior Approvals and Expanded Authority sections of the GPS. These requirements also apply to subawards to foreign entities under financial assistance arrangements, rather than acquisition of goods or services.

If you make a subaward to a foreign entity, to comply with audit requirements, you must include oversight methods. These may include reviewing reports, on-site reviews, or alternatives to a single audit, if one will not be available during the period of the subaward.

Federal Institutions and Payments to or on Behalf of Federal Employees Under Awards

Most policies contained in the GPS apply to awards made to federal institutions. This section includes specific exceptions and modifications of general GPS requirements for federal recipients. It also highlights other related policies.

Eligibility

Specific eligibility is in each NOFO. An awarding agency may not issue an award to any component of its own organization.

PHS organizational segments, other than IHS hospitals, may receive award support under exceptional circumstances only. Such circumstances may include when the work cannot be supported within the mission of the PHS agency and cannot be performed elsewhere.

The federal agency or department is the official applicant, regardless of where within it the work is to be performed. A federal institution must ensure that its own authorizing legislation allows it to receive awards and to be able to comply with the award terms and conditions.

A document that assures both the assumption of responsibility and authority to receive an award must accompany each new and competing continuation application. The assurance must be signed by the head of the responsible federal department or independent agency or a designee who reports directly to the department or agency head. This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

For-Profit Organizations

General

Terms and conditions for for-profit organizations vary from standard ones. Also, terms and conditions for SBIR and STTR programs vary from those usually applied to for-profit organizations.

Cost Principles

Usual cost principles do not specifically apply to for-profit organizations. As a result, use:

- For for-profit organizations: FAR, 48 CFR § 31.2.
- For private hospitals: 45 CFR part 75, appendix IX.

Allowable and Unallowable Costs

Allowable Costs

- Indirect costs
- Travel that does not exceed costs established by the Federal Travel Regulation (FTR).

Unallowable Costs

- Independent research and development costs, as provided in 45 CFR § 75.476.
- Profits or fees, except for awards under the SBIR and STTR programs and funds paid to a contractor for routine goods or services.

Consult the GMS for questions on costs.

Administrative Requirements

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management.

- Equipment: For-profit groups must track equipment. You can't use award-funded equipment to compete unfairly by offering paid services. Any fees charged for using the equipment count as program income and you must report it on the FFR.
- Intellectual property: All for-profit groups, regardless of size, follow the intellectual property rules in 37 CFR § 401. For-profit organizations have different invention reporting rules than non-profits. For-profit organizations can assign invention rights to others without agency approval, but they must still report each invention. The federal government will keep information about federally supported inventions confidential, as allowed by law.
- Program income: See Program Income.
- Operating authorities: Standard award terms apply to for-profit organizations. However, some policies do not allow automatic carryover of unobligated fund balances. The NoA specifies the disposition of the reported unobligated balance.
- Audit: Requirements for non-federal audits of for-profit organizations are in 45 CFR § 75.501. For-profit organizations are subject to requirements for non-federal audits. See Audit Requirements.
- Labor distribution requirements: Salary and wage amounts charged to awards for personal services must:
    - Be based on an adequate labor distribution system that distributes payroll costs in line with generally accepted practices of like organizations.
    - Align to industry standards.
    - Track time spent on award activities. The time and-effort reporting system used must:
    - Be for both professional and other staff
    - Reflect daily reporting
    - Track time by individual projects and indirect activities
    - Record both hours worked, and hours absent
    - Enable the AOR to meet the requirement to certify time entries at least every pay period.
    - The GMS must approve any alternative system.

Small Business Innovation Research and Small Business Technology Transfer Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have three stages. Some projects might not be eligible for all three.

Phase I

Before providing Phase II support, this phase assesses:

- The technical merit and feasibility of proposed research or R&D
- The quality of the applicant's performance

Phase II

This phase advances efforts started in Phase I. These policies apply:

- Funding is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.
- Only Phase I recipients can apply for Phase II funding.
- You can only submit Phase II applications before a Phase I award if using the Fast-Track application process (see below).
- You must submit non-Fast-Track Phase II applications within the first six receipt dates after the end of your Phase I budget period. This is typically two years.

Phase III

The SBIR and STTR programs do not fund Phase III. This phase is for the SBC to work to commercialize the results of the research or R&D done in Phases I and II. In some cases, a federal agency may:

- Use non-SBIR and STTR funds to continue the work.
- Contract for items for federal use.

SBIR and STTR

STTR

The STTR program focuses on teaming a Small Business Concern (SBC) with a non-profit research body for a project that might be turned into a product.

The program requires:

- The SBC collaborates with a single non-profit research institution.
- The SBC must do at least 40% of the research. A domestic non-profit organization does at least 30%. This rule is the same for both Phase I and Phase II.
- Eligible research partners include universities, non-profit hospitals, other non-profits research organizations, and federally funded Research and Development Centers.
- The award goes to the SBC. It disperses funds to the research institution.
- The PI must spend at least 10% of their time on the STTR project.

SBIR

The SBIR program requires that SBC employ the PI at least half-time at the time of award and during the project.

Fast-Track Process

The Fast-Track process speeds up decisions and funding for SBIR and STTR Phase II applications. Policies include:

- To be eligible, the project must be scientifically meritorious with a high potential for commercialization.
- Not every agency lets SBCs use Fast-Track. Talk to the agency first before applying.
- If you aren't approved for Fast-Track, your application might go through the regular review.
- With Fast-Track, Phase I and Phase II applications are handled together and usually get one overall score.

For more details, check the SBIR and STTR NOFOs.

Place of Performance and Sources of Materials

All project activities for Phase I and Phase II of SBIR and STTR must be done in the United States. Using a foreign site for research is rare and needs a solid scientific reason. An example includes testing specific patient groups only available abroad. You must attempt to get alternate funding for the part of the work to be done abroad.

If you must buy materials from another country, you must have a good reason and clearly explain it. Approval of such a waiver is rare. The awarding agency reviews each request individually. If you'll need to do this, talk to the GMS before you apply.

GMSs decide waiver requests. The NoA will clearly state if it is approved.

Change in Organization Status & Change of Recipient Institution Actions

The awarding agency makes eligibility decisions at the initial award time.

A later event like a merger or successor-in-interest could alter the organization's status. If the change makes the organization ineligible for the SBIR or STTR program:

- Any current awards can still proceed unless the small business concern makes a material misstatement that the agency decides poses a risk to national security; or there is a change in ownership, change to entity structure, or other substantial change in circumstances of the small business concern that the Federal agency decides poses a risk to national security
- After that, the organization will not qualify for new SBIR or STTR awards

If an SBIR or STTR award needs to be transferred to a different institution or organization, this new entity must also fulfill the eligibility requirements of the SBIR or STTR program.

Contact the awarding agency to discuss options when considering a move to a new organization.

Minimum Level of Effort

Congress requires minimum levels of effort for these programs.

SBIR required levels of effort:

Program and Phase:	SBC level of effort:	Aggregate payments to others may not exceed:
SBIR Phase I	67%	33%
SBIR Phase II	50%	50%

STTR minimum levels of effort:

Program and Phase:	SBC minimum level of effort:	Single, non-profit research institution minimum LOE:
STTR Phase I	40%	30%
STTR Phase II	40%	30%

Policies include:

- Waivers are not allowed.
- The basis for establishing the percentage of work to be done by each participant is the entire cost (including direct, indirect costs, and fee) related to each party. However, if described and justified under the "Consortium/Contractual Arrangements" section of the application, a different basis might be used.

Multiple Program Director or Principal Investigator Applications and Awards

Team science efforts may use a multiple program director or principal investigator (Multi PD/PI) option. The following policies apply:

- The SBC is always the applicant or recipient organization. Other participants are subcontractors.
- Each PD or PI must commit at least 1.2 calendar months (10% effort) to the project.
- SBIR Phase I and II projects: The contact PD or PI must meet the primary employment requirement. Other PDs or PIs do not have to meet the requirement.
- STTR Phase I and II projects: The PI listed must have a formal appointment with, or commitment to, the SBC. This must be an official relationship but does not require pay.
- Phase IIB Multi PD/PI competing renewal applications: If previously supported through a single PD/PI award, the new application must state the changes in the project's management that led to the proposed Multi PD/PI model.

Public Policy Requirements

Requirements in Appendix D: Administrative and National Policy Requirements apply, unless otherwise noted here or in awarding agency policies.

- Disclosure of financial conflicts of interest does not apply to Phase I of the SBIR and STTR programs.
- Under an SBIR or STTR award, the SBC should purchase only American-made equipment or products when possible.

Allowable Costs and Fees

Program Levels (Total Costs)

The SBA SBIR and STTR Policy Directive provides program levels for SBIR and STTR programs based on statutory guidelines. The directives allow awarding agencies to exceed these levels up to 50% over the guideline when the proposed budget and requested period of support are justified and scientifically appropriate for the proposed research.

In some cases, Phase II SBIR or STTR recipients may apply for Phase IIB competing renewal awards. These are available for projects that require extraordinary time and effort for R&D. Only those SBCs awarded a Phase II may apply for the Phase IIB award.

Applicants must request an appropriate level in the competing application. The awarding agency will not adjust it after submission.

Profit or Fee

SBCs can earn a reasonable profit or fee under Phase I and II of the SBIR and STTR programs.

- This profit or fee must be in the application budget.
- The profit or fee isn't considered a cost for determining allowable use, program income accountability, or setting audit thresholds.
- The SBC can use the profit or fee for any purpose, including investment into the awarded project.
- The intent is to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work. Typically, the profit or fee will not surpass seven percent of the total project costs for each phase.
- The profit or fee should be drawn from PMS in proportion to the drawdown of funds for direct and indirect costs.
- The profit or fee is exclusively for the SBC that receives the award. However, in line with regular commercial practices, the SBC can pay a profit or fee to a contractor that provides routine goods or services under the award.

Indirect Costs

If the applicant SBC has a currently effective indirect cost rate with a federal agency, the rate should be used when calculating proposed indirect costs for an application. The rates must be adjusted for IR&D expenses, which are not allowable under HHS awards.

If that applicant does not have an approved indirect cost rate, one can be proposed in the application. See below for specific requirements for each phase. If awarded at a rate, indirect costs cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with a federal agency. The awarding agency will not negotiate indirect cost rates for Phase I awards.

If you do not have an effective negotiated indirect cost rate, you may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs. You can charge only actual indirect costs to projects.

Phase II

If you do not have an effective negotiated indirect cost rate, you may propose an estimated indirect rate in the application.

If the requested rate is 40 percent of total direct costs or less, you do not need to provide further justification. You can charge only actual indirect costs to projects.

If you choose to negotiate an indirect cost rate greater than 40%, DFAS is the appropriate agency. Upon request, provide DFAS with an indirect cost proposal and supporting financial data for your most recently completed fiscal year. If you do not have financial data for the most recently completed fiscal year, submit a proposal showing estimated rates with supporting documentation.

Administrative Requirements

Market Research

HHS will not support market research, including studies of the literature that lead to a new or expanded statement of work.

No SBIR or STTR funds, direct or indirect, can be used to support commercialization.

For SBIR and STTR programs, market research is the systematic gathering, editing, recording, computing, and analyzing of data relating to the sale and distribution of the research subject. It includes research on:

- The size of potential markets and potential sales volume
- Identifying consumers most apt to purchase the products
- The advertising media most likely to stimulate their purchases

Market research does not include activities that include a public survey to determine the research subject's impact on the behavior of individuals.

Intellectual Property

The recipient keeps rights to data and software created with award funding. However, the federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use the material and to authorize others to do so for Federal purposes.

For SBIR and STTR awards, unlike other commercial awards, such data cannot be released outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

Data Rights

Section 9 of the Small Business Act, as amended (15 USC 638), allows SBC's under an SBIR or STTR award to retain their data rights for at least four years. The SBIR/STTR Policy Directive applies the following data rights:

- The Act allows small business concerns (SBCs) to keep the rights to data they create while working on an SBIR/STTR award. This helps encourage SBCs to participate in Federally funded research and supports them in commercializing their technology. The Federal Government will have access to this data to assess the projects and use the results, but it cannot use the data in ways that would hurt the SBC's rights or economic opportunities. The SBIR/STTR data rights provisions and definitions ensure that the Federal Government effectively protects properly marked SBIR/STTR data during the SBIR/STTR protection period just as well as it protects data developed at private expense.
- Federal agencies that participate in SBIR/STTR awards must make sure that SBC recipients keep appropriate proprietary rights to data generated while working on an award. In general, this means the Federal Government will have rights to that data during the protection period, except for certain types of data that are not subject to such data rights restrictions.
- SBIR/STTR data rights apply to all SBIR/STTR awards, including subcontracts, for all phases of the program (I, II, or III) as defined by the SBA Policy Directive from May 2, 2019. The rights for Phase III awards are the same as those for Phases I and II.
- SBIR/STTR data rights restrict the Federal Government's use and release of properly marked SBIR/STTR data only during the SBIR/STTR protection period. After the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes. At this time, the Federal Government is relieved of disclosure prohibitions related to such government purposes and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.

SBIR/STTR Data Rights - Main Elements:

- An SBC retains title and ownership of all SBIR/STTR data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR data that are not granted to the Government in accordance with the SBA Policy Directive. These rights of the SBC do not expire.
- The Government receives SBIR/STTR data rights during the SBIR/STTR protection period on all appropriately marked SBIR/STTR data. These rights enable the Federal Government to use SBIR/STTR data in limited ways within the Government, such as for project evaluation purposes. These rights are intended to prohibit use and disclosure of SBIR/STTR data that may undermine the SBC's future commercialization of the associated technology. The Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.
- After the SBIR/STTR protection period has expired, the Federal Government may use, and authorize others to use on its behalf, for government purposes, SBIR/STTR data that was subject to SBIR/STTR data rights during the SBIR/STTR protection period.
- The SBIR/STTR protection period begins with award of an SBIR/STTR funding agreement. It ends twenty years, or longer at the discretion of the participating agency, from the date of award of an SBIR/STTR award (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless the agency and the SBC negotiate for some other protection period for the SBIR/STTR data subsequent to the award.
- Any SBIR/STTR data that is delivered must be marked with the appropriate SBIR/STTR data rights legend or notice to receive the protections given to SBIR/STTR data pursuant to SBIR/STTR data rights. The Government is not liable for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR data that is not appropriately marked in line with agency procedures. If SBIR/STTR data is delivered without the required legend or notice, the SBIR/STTR recipient may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR data legend or notice, as applicable, placed on qualifying data. If SBIR/STTR data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the recipient's expense.

Negotiated Rights:

- An agency must not, in any way, make issuance of an SBIR/STTR award conditional on the SBC negotiating or consenting to negotiate a special license or other agreement regarding SBIR/STTR data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
- After issuance of an SBIR/STTR award, the SBC may enter into a written agreement with the agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR protection period. However, the agreement must be

entered into voluntarily, by mutual agreement of the SBC and agency. The agreement cannot be a condition for additional work under the funding agreement or the exercise of options. The agreement must be entered into only after the SBIR/STTR award, which must include an appropriate SBIR/STTR data rights clause, has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR funding agreement is signed. A decision by the recipient to relinquish, transfer, or modify in any way its rights in SBIR/STTR data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR data rights shall have no effect on the provision of SBIR/STTR data rights in a resulting Phase I, Phase II, or Phase III award.

- To ensure that SBIR/STTR recipients receive the applicable data rights, all SBIR and STTR NOFOs and resulting funding agreements must fully implement all of the policies, procedures, and requirements set forth in the SBA Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR NOFOs and awards. The SBA Policy Directive provides a sample SBIR/STTR data rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.
- The STTR program requires that the SBC and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research.

SBIR and STTR recipients are covered by 35 USC 200-212 and 37 CFR § 401 with respect to inventions and patents.

Data Sharing

For SBIR Phase II funding over $500,000 in a year in direct costs, applicants must follow the GPS on data sharing, unless the Small Business Act conflicts. If the data is proprietary or sensitive, the SBC should explain it in the application. Whether or not the award meets the threshold for data sharing under Intellectual Property, HHS won't share data outside the federal government without recipient approval for a period of 20 years from completion of the project.

For more information, please see NIH's SBIR/STTR information page.

Research Awards

Human Subjects in Research

The regulation for all HHS awards involving human subjects research is 45 CFR part 46, Basic HHS Policy for Protection of Human Subjects. Subpart A is also known as the Common Rule. These regulations

implement Section 491(a) of the Public Health Service (PHS) Act. These regulations apply to both domestic and foreign organizations.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy.

All NOFOs will clearly state:

- The parameters of human subject use
- The information and assurances required from you prior award

There is a single version of the Federal-wide Assurance (FWA) form and Terms of Assurance for domestic and international institutions.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities (45 CFR § 46.101(a) and 45 CFR § 46.103(a)).

Recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

Exemptions

Some human subject research is exempt from the requirements of the HHS regulations.

The categories of research that qualify for exemption are found at 45 CFR § 46.104(d)(1)-(8). HHS has final authority to decide if a particular research study supported by HHS is exempt from the HHS regulations. OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in 45 CFR § 46.101(c) regarding whether a particular activity is regulated by 45 CFR part 46. Contact OHRP for questions.

Policies for Non-Exempt Human Subjects Research

The recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA (45 CFR § 46.103(a)).
- Certify to the awarding agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA (45 CFR § 46.103(d)).

The OHRP website contains a listing of those organizations with OHRP-approved assurances.

The awarding agency must make sure an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award unless there is a specific condition in the NoA restricting expenditures for this purpose.
- You initiate human subjects research, and the awarding agency removes any related NoA specific condition.
- Approving a post-award change in scope that will result in human subjects research.

The specific award condition must indicate that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving human subjects at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.

The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Research Involving Animals and Their Welfare

Requirements for using live, vertebrate animals apply to all PHS agencies and other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, OASH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).
- Incorporate the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training.
- Require the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals.
- Require compliance, as applicable, with the Animal Welfare Act and other federal statutes and regulations relating to animals.

You must establish appropriate policies and procedures to ensure the humane care and use of animals, and you are ultimately responsible for compliance with the PHS Policy.

You can get information about animal welfare topics from the Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW. The list of organizations with approved assurances is on the OLAW website for both domestic institutions and foreign institutions.
- Verify, as part of the application or before award, current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. PHS Policy requires that IACUC approval must have happened within three years of the period of performance start date for new or renewal awards and at least every three years after that.
- Comply with the awarding agency's internal IACUC requirements if a cooperative agreement.

If you do not have a current Animal Welfare Assurance (or made alternative arrangements, like an inter-institutional assurance acceptable to OLAW) or has not provided the required verification by the

time an award is to be made, the awarding agency will notify the PO and the applicant. The awarding agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals.
- Include a specific condition in the NoA restricting expenditures.

The award condition must state that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving animals at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.
- The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Before approving changes involving animal research after award, the awarding agency needs to confirm that there's a proper Animal Welfare Assurance with OLAW. They also need verification from the IACUC.

Reporting

Reporting requirements under the PHS Policy include an annual report to OLAW describing:

- Any updates in your animal care program as mentioned in the Assurance.
- Changes in IACUC membership
- The dates when the IACUC reviewed your program and facilities.

Lastly, the IACUC must quickly report any serious issues or breaches in policies, guidelines, or any suspensions through the official who signed the Assurance.

Foreign Applicants

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which includes:

- Institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted
- A commitment to follow the International Guiding Principles for Biomedical Research Involving Animals.

Awards to Individuals

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy.

Appendix D: HHS Administrative and National Policy Requirements

Please go to the following page to see updated HHS requirements:
https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf

Additional Information on Uniform Administrative Requirements

As stated in the information linked above, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75) apply to all HHS awards, unless specifically exempted by 45 CFR § 75.101(d) or (e).

As of October 1, 2024, the following provisions from 2 CFR part 200 are effective for all new HHS awards or monetary actions (new, continuation, and supplements):

2 CFR § 200.1 Definitions: Modified Total Direct Cost (MTDC), which increases the exclusion threshold of subawards from $25,000 to $50,000 for modified total direct costs, definition of Equipment, which increases the threshold for determining equipment from $5,000 to $10,000, definition of Supplies, which increases the threshold for determining supplies from $5,000 to $10,000;

2 CFR § 200.313 (e) Equipment: Increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency" (*see 2 CFR section 200.313(e)(1)*). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.

2 CFR § 200.314(a) Unused Supplies: Increases from $5,000 to $10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items (*see 2 CFR section 200.314*).

2 CFR § 200.320 Micro-purchase Threshold: Increases the micro-purchase threshold to $50,000 (*see 2 CFR 200.320*).[1]

2 CFR § 200.333 Fixed Amount Awards Subawards: Increases from $250,000 to $500,000 the amount of fixed amount subawards that a recipient may provide with prior written approval from the Federal agency (*see 2 CFR section 200.333*).

2 CFR § 200.344 Closeout: Increases the time period for recipients to submit final reports in support of closeout of the award from 90 to 120 days (*see 2 CFR 200.344*).[2]

2 CFR § 200.414(f) De Minimis Indirect Rate: Increases from 10% to 15% the rate that recipients of Federal funds may use for indirect costs without negotiating an alternative rate with the relevant

[1] This provision has already been adopted by HHS by operation of law, Pub. L. No. 115-91, and OMB Memorandum 18-18. It is included to be clear that this regulation is in force for HHS.

[2] This provision has already been adopted by HHS. See 88 FR 63591 (Sept. 15, 2023). It is included to be clear that this regulation is in force for HHS.

Federal agency (*see 2 CFR section 200.414*). Note that this does not apply to HHS Training or Foreign awards, for which HHS proposes to maintain a modification that caps the de minimis at 8%.

2 CFR § 200.501 Single Audit: Increase from $750,000 to $1,000,000 the level at which a recipient of Federal funds is required to conduct a single audit or a program specific audit (*see 2 CFR section 200.501*).

Appendix E: Financial Assistance General Certifications and Representations

In almost all instances, applicants must have a SAM.gov registration. Agreement to a list of general certifications and representations is required for registration.

Please go to the following page to see updated Certifications and Representations:

https://www.hhs.gov/sites/default/files/financial-assistance-general-certification-representations.pdf